

**TAB 336**

Palmetto DMERC (Robin K. Stone)  
Columbia, SC

October 14, 2009

1

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

-----x  
IN RE PHARMACEUTICAL INDUSTRY :  
AVERAGE WHOLESALE PRICE : MDL NO. 1456  
LITIGATION : MASTER FILE NO. 01-CV-12257-PBS  
-----x SUBCATEGORY NO. 06-CV-11337-PBS  
THIS DOCUMENT RELATES TO :  
UNITED STATES OF AMERICA EX REL. : JUDGE PATTI B. SARIS MAGISTRATE  
VEN-A-CARE OF THE FLORIDA KEYS, : JUDGE MARIANNE B. BOWLER  
INC., ET AL. V. BOEHRINGER :  
INGELHEIM CORPORATION, ET AL., :  
CIVIL ACTION NO. 07-10248-PBS :  
and :  
UNITED STATES OF AMERICA EX REL. : OCTOBER 14, 2009  
VEN-A-CARE OF THE FLORIDA KEYS, : 12:03 P.M.  
INC., ET AL. V. DEY LABORATORIES. :  
-----x

VIDEOTAPE DEPOSITION OF:

30(b)(1) and 30(b)(6) REPRESENTATIVE  
OF PALMETTO DMERC (ROBIN K. STONE)

TAKEN AT:

Law Offices of Nelson, Mullins,  
Riley & Scarborough  
1320 Main Street, 17th Floor  
Columbia, SC

REPORTED BY: TERRI L. BRUSSEAU, RPR, CRR

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2 (Pages 2 to 5)

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3 (Pages 6 to 9)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
<p style="text-align: center;"><b>STIPULATION</b></p> <p>It is stipulated by and among Counsel that this deposition is being taken in accordance with the Federal Rules of Civil Procedure; that all objections as to Notice of this deposition are hereby waived; that all objections except as to form are reserved until the time of trial; and that the witness waives reading and signing of this deposition.</p> <p style="text-align: center;">* * * * *</p>	<p>6</p> <p>1 Corporation, et al., Civil Action Number 2 07-10248-PBS and also cross-noticed in the United 3 States of America ex rel. Ven-A-Care of the 4 Florida Keys, Incorporated, et al., versus Dey 5 Laboratories, Master File Number 01-CV-12257-PBS 6 in the United States District Court for the 7 District of Massachusetts.</p> <p>8 And if counsel now identify yourselves.</p> <p>9 MR. GORTNER: Eric Gortner from 10 Kirkland &amp; Ellis representing Roxane Laboratories 11 and Boehringer Ingelheim Corporation and related 12 entities.</p> <p>13 MR. FAUCI: Jeff Fauci on behalf of the 14 United States.</p> <p>15 MR. WALKER: Kendall Walker for 16 Palmetto GBA, I'm in-house counsel for Blue Cross 17 and Blue Shield of South Carolina.</p> <p>18 VIDEO TECHNICIAN: And would the Court 19 Reporter now swear in the witness.</p> <p>20 MR. GORTNER: We have someone on the 21 phone, I believe.</p> <p>22 MS. LORENZO: This is Marisa Lorenzo</p>
<p>1 (Exhibit Roxane 252, Exhibit 98, 2 Exhibit to the July 24, 2009 Declaration of 3 George B. Henderson, II In Support of Plaintiffs' 4 Motion For Partial Summary Judgment and In 5 Opposition To Dey's Motion For Partial Summary 6 Judgment, was marked for identification.)</p> <p>7 VIDEO TECHNICIAN: We are now on the 8 record. Today's date is October 14th, 2009. The 9 time is 12:02 PM. This is the videotape 10 deposition of Robin Kreush Stone, 30(b)(1) and 11 30(b)(6) representative of Palmetto DMERC, taken 12 by counsel for the Defendant. The location is 13 Nelson Mullins, 1320 Main Street, 17th Floor, 14 Columbia, South Carolina.</p> <p>15 My name is Alan Metts, legal 16 videographer, representing Henderson Legal 17 Services. The Court Reporter is Terri Brusseau. 18 This deposition is taken in the matter of the 19 Pharmaceutical Industry Average Wholesale Price 20 Litigation relating to the United States of 21 America ex rel. Ven-A-Care of the Florida Keys, 22 Incorporated, et al., versus Boehringer Ingelheim</p>	<p>7</p> <p>9</p> <p>1 from Kelley, Drye &amp; Warren for the Dey 2 defendants.</p> <p>3 VIDEO TECHNICIAN: I couldn't hear her, 4 I'm sorry.</p> <p>5 MR. GORTNER: Hey, Marisa, could you 6 speak up a little bit?</p> <p>7 MS. LORENZO: Sure. This is Marisa 8 Lorenzo from Kelly Drye &amp; Warren for the Dey 9 defendants.</p> <p>10 VIDEO TECHNICIAN: And would the Court 11 Reporter now swear in the witness.</p> <p>12 ROBIN K. STONE being first duly 13 sworn, testified as follows:</p> <p>14 MR. FAUCI: And before we begin, I just 15 want to state for the record that although the 16 deposition was noticed 30(b)(1), the parties 17 don't have any objection to this being both 18 30(b)(1) and 30(b)(6) deposition testimony 19 consistent with Mrs. Stone's prior testimony as a 20 30(b)(6) witness for Palmetto DMERC.</p> <p>21 EXAMINATION 22 BY MR. GORTNER:</p>

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4 (Pages 10 to 13)

<p>10</p> <p>1 Q. Good afternoon, Mrs. Stone. As you 2 know, my name is Eric Gortner. I represent 3 Roxane defendants and certain companies that have 4 been sued by the Department of Justice involving 5 certain Medicare claims. I'm aware that you have 6 been deposed before in this case sometime earlier 7 in 2008, is that right?</p> <p>8 <b>A. That's right.</b></p> <p>9 Q. And you're familiar with the general 10 rules of a deposition which include that all 11 answers need to be spoken answers, head nods and 12 head shaking won't work?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. And it will be helpful to the extent 15 that you're able to speak up loudly and clearly 16 so that the Court Reporter who is taking down 17 every word that you say can hear it, that will be 18 helpful. And the other thing that we should try 19 to do as best as we're able is to not talk over 20 each other so there may be some times where you 21 will anticipate where my question is likely to 22 end. I'll ask you as best as possible to</p>	<p>12</p> <p>1 Q. Right.</p> <p>2 <b>A. Bunker Henderson and Jeff Fauci.</b></p> <p>3 Q. And do you know on or about when they 4 contacted you to prepare this declaration?</p> <p>5 <b>A. I can't remember the exact dates but I 6 want to say probably a few months ago.</b></p> <p>7 Q. I'm sorry, look -- if you look at the 8 back of the document, maybe this will help 9 refresh your recollection. The document says it 10 was -- that you executed the signature on July 11 23rd, 2009. Do you recall whether you were 12 contacted some -- a few days before July 23rd, a 13 week, two weeks, something like that?</p> <p>14 <b>A. I don't remember the exact date prior 15 to July 23rd.</b></p> <p>16 Q. Okay. Do you think it was a couple 17 days?</p> <p>18 <b>A. I don't remember. I mean, I received 19 e-mails, you know, and things like that, you 20 know, notifying me that this was coming down but 21 I don't remember the exact dates.</b></p> <p>22 Q. And who e-mailed you?</p>
<p>11</p> <p>1 patiently wait for me to finish the question so 2 that we can get clear questions and answers on 3 the transcript.</p> <p>4 <b>A. Okay.</b></p> <p>5 Q. And you understand that you're under 6 oath, of course?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. If at any point I ask a question that 9 you don't understand, feel free to ask me to 10 clarify the question and I'll do the best I can.</p> <p>11 <b>A. Okay.</b></p> <p>12 Q. I'm going to hand you what we have 13 premarked as Roxane Exhibit 252 and this is a 14 declaration that you prepared in the Department 15 of Justice Roxane matter. Do you recognize that 16 document?</p> <p>17 <b>A. Yes, I do.</b></p> <p>18 Q. I was hoping to get a little bit of a 19 background in terms of how this -- how you came 20 to be involved in this document. Can you tell me 21 who contacted you?</p> <p>22 <b>A. For this particular document?</b></p>	<p>13</p> <p>1 <b>A. I want to think it started out with 2 Bunker Henderson.</b></p> <p>3 MR. FAUCI: I'll just counsel the 4 witness to be cautious -- being cautious to not 5 answer any questions regarding the substance of 6 your communications with either myself or Mr. 7 Henderson but proceed for right now.</p> <p>8 THE WITNESS: Okay. I don't recall the 9 exact dates. My day-to-day schedule is very busy 10 and I don't keep track of time in that manner. 11 This, as it states, was signed on July 23rd. I 12 do not recall, you know, if it was days before 13 that or may have been a week before that. In 14 reference to the declaration there were, you 15 know, other requests as far as notification 16 notifying me that this was coming down which I 17 believe may have been like the 1st of July 18 because I think the first communication was when 19 I was going on vacation, which was during that 20 time period.</p> <p>21 MR. GORTNER: Jeff, what's the basis of 22 your objection about the contacts between Bunker</p>

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5 (Pages 14 to 17)

<p>14</p> <p>1 and you and Mrs. Stone?</p> <p>2 MR. FAUCI: A, I wasn't trying to make</p> <p>3 an objection but, B, the government -- the United</p> <p>4 States is certainly taking the position that</p> <p>5 Palmetto is a government contractor who</p> <p>6 administers a federally-funded program pursuant</p> <p>7 to federal contracts that Miss -- the government</p> <p>8 has consistently and continues to take the</p> <p>9 position that the attorney/client privilege</p> <p>10 encompasses communications between employees of</p> <p>11 DMERC and the United States.</p> <p>12 MR. GORTNER: Any communications</p> <p>13 rendering legal advice, right?</p> <p>14 MR. FAUCI: Yes, which would include</p> <p>15 communications regarding the drafting of this</p> <p>16 affidavit. We can address this on a --</p> <p>17 MR. GORTNER: Okay.</p> <p>18 MR. FAUCI: I haven't counseled her not</p> <p>19 to answer any specific questions and I cautioned</p> <p>20 her to be careful in what she answers and I think</p> <p>21 we can handle it on a case-by-case basis.</p> <p>22 BY MR. GORTNER:</p>	<p>16</p> <p>1 in Roxane Exhibit 252, those aren't words that</p> <p>2 you wrote?</p> <p>3 MR. FAUCI: Objection to form.</p> <p>4 THE WITNESS: I provided -- I mean, I</p> <p>5 didn't, of course, write every detail but I gave</p> <p>6 them, you know, my input to these items here.</p> <p>7 It's not word-for-word verbatim but the content</p> <p>8 of it I approved.</p> <p>9 BY MR. GORTNER:</p> <p>10 Q. Okay. So the way --</p> <p>11 <b>A. The final content.</b></p> <p>12 Q. I'm sorry, I didn't mean to interrupt</p> <p>13 you. So the way it worked mechanically was phone</p> <p>14 conversations back and forth to the Department of</p> <p>15 Justice attorneys, you then, I presume, saw a</p> <p>16 draft of Roxane Exhibit 252 and reviewed it for</p> <p>17 content and approved it?</p> <p>18 <b>A. This is 252? Yes.</b></p> <p>19 Q. Were there different versions that you</p> <p>20 reviewed?</p> <p>21 <b>A. There was another version I believe in</b></p> <p>22 <b>which, you know, I clarified what would be</b></p>
<p>15</p> <p>1 Q. Do you recall what the content of the</p> <p>2 e-mails were that were sent to you by Bunker and</p> <p>3 Mr. Fauci?</p> <p>4 <b>A. Just notifying me that I would be</b></p> <p>5 <b>deposed at one point and there was some</b></p> <p>6 <b>communication regarding, you know, the CD's that</b></p> <p>7 <b>we used, CD's --</b></p> <p>8 Q. You're talking about the Redbook CD's?</p> <p>9 <b>A. Yeah.</b></p> <p>10 Q. You're referring to the additional CD's</p> <p>11 that were produced in this case?</p> <p>12 <b>A. Right.</b></p> <p>13 Q. Sometime this summer?</p> <p>14 <b>A. Right.</b></p> <p>15 Q. Well, let's just stick for now in terms</p> <p>16 of this declaration that you submitted. Did you</p> <p>17 have conversations with Mr. Fauci and Mr. Bunker</p> <p>18 about the contents of this declaration?</p> <p>19 <b>A. Just, you know, confirming that I could</b></p> <p>20 <b>attest to, you know, everything that I've said in</b></p> <p>21 <b>here.</b></p> <p>22 Q. Now, I take it that the words that are</p>	<p>17</p> <p>1 <b>correct.</b></p> <p>2 Q. And what was the subject matter of what</p> <p>3 you clarified?</p> <p>4 MR. FAUCI: Objection to form. And</p> <p>5 again, I counsel Miss Stone not to get into any</p> <p>6 of the details of conversations between Mr.</p> <p>7 Henderson or myself.</p> <p>8 BY MR. GORTNER:</p> <p>9 Q. With that instruction answer the</p> <p>10 question as best you can.</p> <p>11 <b>A. Okay. I don't recall exactly which</b></p> <p>12 <b>ones but there were a few, you know, things that</b></p> <p>13 <b>based on my conversation, you know, when written</b></p> <p>14 <b>that I disagreed with and they went back and</b></p> <p>15 <b>corrected them.</b></p> <p>16 Q. Did any of those corrections have to do</p> <p>17 with the classification of the NovaPlus</p> <p>18 Ipratropium Bromide product?</p> <p>19 MR. FAUCI: Objection to form, same</p> <p>20 instruction.</p> <p>21 THE WITNESS: I'm not sure exactly</p> <p>22 which ones I had disagreed with. They were very,</p>

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<p>18</p> <p>1 you know, minor. I'm not sure which ones exactly 2 I may have had them change the verbiage on.</p> <p>3 BY MR. GORTNER:</p> <p>4 Q. That's okay. When we go through the 5 declaration, if anything triggers your memory let 6 me know, okay?</p> <p>7 A. Okay.</p> <p>8 Q. Now, in reviewing this declaration and 9 discussing the content of it, did you talk to any 10 other Palmetto DMERC employee regarding this 11 declaration?</p> <p>12 A. No.</p> <p>13 Q. So is it fair to say that the content 14 of what's in your declaration that we've marked 15 as Roxane Exhibit 52, it's all based upon your -- 16 either your memory or recollections or the 17 information that you knew?</p> <p>18 A. That is correct.</p> <p>19 Q. So you didn't go back to anyone who 20 worked on the pricing arrangements and ask them 21 about the NovaPlus product, is that right?</p> <p>22 A. No.</p>	<p>20</p> <p>1 Q. What was the information that you 2 looked at?</p> <p>3 A. The arrays and the various files that 4 we had provided with the dec -- well, not the 5 declaration, but the suit itself.</p> <p>6 Q. What are the various files you're 7 talking about?</p> <p>8 A. Just array files, the fee calculation 9 array files, looked at procedures, looked at 10 another file that categorized products brand 11 versus generic.</p> <p>12 Q. Anything else?</p> <p>13 A. I mean, those were the files, you know, 14 that I was provided, you know, that I was looking 15 at, the array files. I'm trying to think. I 16 don't think there was anything else. The array 17 files, the procedures. Oh, the Redbook CD's.</p> <p>18 Q. Okay. And you mean the CD/ROM's?</p> <p>19 A. Yes.</p> <p>20 Q. And you were able to actually open 21 those up and look at them?</p> <p>22 A. Um-hum.</p>
<p>19</p> <p>1 Q. I'm sorry, the answer was no?</p> <p>2 A. No.</p> <p>3 Q. Just a slight pause, make sure we don't 4 overlap. No, it's okay.</p> <p>5 A. I'm sorry.</p> <p>6 Q. Now, in preparing this declaration, did 7 you, yourself, go back and look at the Palmetto 8 pricing range where the NovaPlus product was 9 included?</p> <p>10 A. Yes, I did.</p> <p>11 Q. Did you look at all of them?</p> <p>12 A. I went back and skimmed through some of 13 my files and other files that were -- you know, 14 that I had available to me just to make sure that 15 I was correct in not recalling.</p> <p>16 Q. Let me stop there for a second. When 17 preparing this declaration, did you have a 18 specific memory of the Roxane NovaPlus 19 Ipratropium Bromine products and how they had 20 been categorized in the Palmetto arrays?</p> <p>21 A. When initially prepared, no. I had to 22 go back and look at the information.</p>	<p>21</p> <p>1 Q. Okay. And what did you look at on 2 those CD's, do you recall?</p> <p>3 A. Just looking at the way different 4 things worked, how they -- how the data was 5 presented because I wasn't very familiar, I 6 didn't work real closely with the CD's, and just 7 going back and trying to look at them in 8 comparison to the hard copy manuals.</p> <p>9 Q. When you say hard copy manuals --</p> <p>10 A. The annual hard copy books, Redbook.</p> <p>11 Q. The Redbook manual?</p> <p>12 A. Yes.</p> <p>13 Q. You said a moment ago that the files 14 that were provided to me. I wanted to understand 15 what you meant by that. You mean that -- who 16 provided those files to you? Did you select them 17 or did someone provide them to you?</p> <p>18 A. There were just things that, you know, 19 I was asked to kind of look over and get familiar 20 with to see, you know, if what I had stated here 21 by looking at them still held -- was true.</p> <p>22 Q. And what did the fee calculation or the</p>

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<p>22</p> <p>1 arrays, what did that tell you about whether what 2 you said in the declaration was true?</p> <p>3 <b>A. Well, some of the fees --</b></p> <p>4 MR. FAUCI: Objection to form.</p> <p>5 BY MR. GORTNER:</p> <p>6 Q. You can answer.</p> <p>7 <b>A. Okay. Some of the fees of the fee</b></p> <p>8 <b>array, the way it was structured, it had a G on</b> <b>the end of the file, which insinuated or could</b> <b>have been speculated that these sources were</b> <b>considered generic but that wasn't the case.</b></p> <p>9 <b>That was the basis of the fee calculation being</b> <b>based on generic and therefore it was misleading.</b></p> <p>10 Q. Let me stop you right there. What I'd 11 like to do is why don't I pull out the actual -- 12 what we have been calling the arrays but you may 13 also be calling the fee calculation. Let me get 14 those documents so we can look at them together 15 and make sure we're on the same page, okay?</p> <p>16 This is a document that's previously 17 been marked as Roxane Exhibit 46. And maybe you 18 could turn to -- it may be useful to turn to --</p>	<p>24</p> <p>1 for this quarter, for these J codes, the fee was 2 set based upon the median of the generics, is 3 that right?</p> <p>4 <b>A. Yes.</b></p> <p>5 Q. And in every instance in these arrays 6 when the source column has a G in it, it means 7 that the actual fee that Palmetto set to pay for 8 Medicare claims for that particular J code was 9 based upon the median generic, not on a brand, 10 right?</p> <p>11 <b>A. That's what my research of the</b> 12 <b>documents I was looking at.</b></p> <p>13 Q. And then at a later point in time the 14 -- which may have coincided with you switching to 15 an SAS program, I'm not sure if that's correct, 16 but there's a -- there's not -- the source column 17 changes to a term that I think says O type. And 18 if you want, you can flip these to 0075, a couple 19 pages over, and you can see that there's now a 20 far right column that I read as O type on the far 21 right that has that same G and B designation, do 22 you see that?</p>
<p>23</p> <p>1 how about the page that's Bates labeled 2 AWQ022-0071. They're consecutive so the 71 might 3 get you where you are. And what I think you were 4 just referring to in your testimony is that far 5 right-hand column on this chart and on this 6 particular page, the one that's Bates labeled 7 0071, you can see that the Ipratropium Bromide 8 NovaPlus products are there in the middle of the 9 page and I think you were testifying as to that 10 far right column that has either a G or a B in 11 it?</p> <p>12 <b>A. Um-hum.</b></p> <p>13 Q. And what I believe you were just saying 14 or what you said in your declaration is that your 15 understanding of that column is that that 16 reflects whether the fee that was ultimately set 17 for that particular J code, whether it was set up 18 on a brand drug or a brand source, which is a 19 generic drug or generic source, is that right?</p> <p>20 <b>A. That's correct.</b></p> <p>21 Q. And what that column -- in reviewing 22 this, what that column told you is that for --</p>	<p>25</p> <p>1 <b>A. Yes.</b></p> <p>2 MR. FAUCI: Objection to form.</p> <p>3 THE WITNESS: O type.</p> <p>4 BY MR. GORTNER:</p> <p>5 Q. I'm sorry, what's that?</p> <p>6 <b>A. It says type.</b></p> <p>7 Q. Okay, type.</p> <p>8 MR. GORTNER: And was that the basis of 9 your objection, Jeff?</p> <p>10 MR. FAUCI: That and I'm not sure what 11 you meant by SAS program.</p> <p>12 BY MR. GORTNER:</p> <p>13 Q. Okay. Let's strike that. I thought 14 Palmetto at one point had changed to an automated 15 program but let's just ignore that, let me go 16 back to this, on this particular array with the 17 Bates label AWQ022-0075. Is it your 18 understanding that that far right column that's 19 either O type or type is in effect representing 20 the same information that the source column 21 represented in the earlier arrays?</p> <p>22 <b>A. Yes.</b></p>

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<p style="text-align: right;">26</p> <p>1 Q. And what that's telling you here is, 2 for instance, J code, J6 -- J7644KO, which you 3 can see at the very bottom of this page, that the 4 payment for not just those drugs but all the 5 drugs under that J code are set by the median 6 generic there?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. And I'll represent to you, Mrs. Stone, 9 in looking over all these arrays, it appears to 10 me that all the Ipratropium Bromide payments for 11 these arrays that are marked in this exhibit have 12 the indication under either the source or the 13 type column that the payment was set by G, by a 14 generic, median generic set the price and not the 15 brand, is that consistent with your recollection?</p> <p>16 <b>A. Can you repeat that again, please?</b></p> <p>17 Q. Sure. In reviewing these arrays that 18 have been marked as Roxane Exhibit 46 on the 19 Palmetto DMERC, I looked at all the entries for 20 payment source for Ipratropium Bromide and the 21 different J codes and in every instance the entry 22 in the source column or the type column had a G</p>	<p style="text-align: right;">28</p> <p>1 <b>the generics because the generics are the -- I 2 mean, the generic was the lowest of the median 3 and of the lowest brand.</b></p> <p>4 Q. Okay. That was really my question. I 5 just wanted to confirm that during the time that 6 Ipratropium Bromide NovaPlus was in the arrays, 7 it didn't set the payment amount, it wasn't based 8 upon its location of the brand array, the payment 9 amount was set based on the median generic?</p> <p>10 MR. FAUCI: Objection to form.</p> <p>11 THE WITNESS: Yes, if it was -- if it 12 was based on generics, the Ipratropium Bromide 13 NovaPlus price would have been considered in 14 developing the fee but if the brand was not 15 lower, then it is based on the median of the 16 generics if it's the lower sources.</p> <p>17 BY MR. GORTNER:</p> <p>18 Q. And that's reflected by a G in either 19 the source column --</p> <p>20 <b>A. That is correct.</b></p> <p>21 Q. -- or the type column? Okay. Now, you 22 said you also reviewed procedures in considering</p>
<p style="text-align: right;">27</p> <p>1 for that particular drug. And my question to 2 you: Is that consistent with your recollection?</p> <p>3 <b>A. I'm not sure I understand exactly what 4 you're saying but I see one here that has a B. 5 If I'm not mistaken I was understanding you to 6 say that they all had G's?</b></p> <p>7 Q. Let me correct the question then. Let's 8 focus on just the time period where Ipratropium 9 Bromide NovaPlus was in the array.</p> <p>10 <b>A. Just NovaPlus?</b></p> <p>11 Q. Yeah. That might make it a little bit 12 easier. And my recollection in reviewing these 13 arrays was that every time that NovaPlus 14 Ipratropium Bromide was in the array, it had a G 15 next to the source column or the type column 16 which according to your testimony suggested the 17 payment was based on the median of the generic 18 prices and not based upon any brand price. Is 19 that consistent with your recollection of how 20 payments occurred?</p> <p>21 <b>A. The payment for all Ipratropium 22 Bromide, my sources would have been based off of</b></p>	<p style="text-align: right;">29</p> <p>1 the content of your declaration. What procedures 2 are you referring to?</p> <p>3 <b>A. Our internal procedures.</b></p> <p>4 Q. And what are those? Are those written 5 down?</p> <p>6 <b>A. Yes, they are.</b></p> <p>7 Q. What are they called?</p> <p>8 <b>A. Drug pricing instructions, procedures.</b></p> <p>9 <b>I don't know the precise name.</b></p> <p>10 Q. Okay. Let me see if I can locate 11 something like that and let me know if this is 12 what you're referring to. I'm going to hand you 13 what's been previously marked as Roxane Exhibit 14 42. It appears to be a December 1, 1999 letter 15 from you to it seems the HCFA central office and 16 the regional administrators. And at the back it 17 has attached a document that's entitled Medicare 18 Professional Reimbursement Desk Procedure and 19 then it has another heading that says Drug 20 Pricing Procedure, Medicare Part A, B, SAD or 21 SADMERC and DMERC. Do you see that document?</p> <p>22 <b>A. Um-hum.</b></p>

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<p style="text-align: right;">30</p> <p>1 Q. Is that what you're referring to by 2 your internal procedures?</p> <p>3 <b>A. Yes.</b></p> <p>4 Q. Okay. And taking a step back, can you 5 just explain to me what is this document, who 6 creates it, who updates it, who uses it?</p> <p>7 <b>A. This is created by the pricing unit 8 which is now Palmetto GBA. Initially it was 9 created as a Part B document, I'm not sure who 10 the initial creator was, and then once we took 11 the DMERC or took on the DMERC contract, we 12 merged it into a standard procedure used by all 13 departments trying to encompass everyone's 14 requirements into one procedure.</b></p> <p>15 Q. Let me stop you there just for a 16 second, Mrs. Stone, make sure I understand what 17 you're saying. You're not sure who initially 18 developed it but is it your understanding it was 19 initially developed by a DMERC or some Medicare 20 carrier? I'm just trying to distinguish whether 21 it was created by HCFA or by a DMERC.</p> <p>22 <b>A. No, it was initially created by Blue</b></p>	<p style="text-align: right;">32</p> <p>1 <b>A. I don't remember when they did all that 2 change.</b></p> <p>3 Q. Okay. And what was the purpose of this 4 document?</p> <p>5 MR. FAUCI: Object to form.</p> <p>6 THE WITNESS: The document provided 7 guidance.</p> <p>8 BY MR. GORTNER:</p> <p>9 Q. To whom?</p> <p>10 <b>A. To the associates doing the 11 calculations.</b></p> <p>12 Q. I'll represent to you that I've seen 13 this document -- or let me correct that. This 14 document has been produced by other DMERC's. Is 15 it your understanding or do you have an 16 understanding whether this document was 17 distributed to other DMERC's like Cigna or 18 Administar?</p> <p>19 <b>A. It probably has been shared as the 20 DMERC's tried to consolidate. I'm not sure if it 21 was shared in that capacity or if it was shared 22 when we were doing some -- this may -- there was</b></p>
<p style="text-align: right;">31</p> <p>1 <b>Cross/Blue Shield as the Medicare Part B carrier 2 for South Carolina. Then when we became the 3 DMERC contractor, those functions were handled in 4 one department or one unit, division, whatever 5 you -- however you want to refer to it, and 6 eventually those procedures were merged together 7 for consistency.</b></p> <p>8 Q. Okay. When did -- when did Blue 9 Cross/Blue Shield or Palmetto, depending on what 10 the designation was, become a DMERC contractor?</p> <p>11 <b>A. In 1992 or '93. I can't recall the 12 exact date because I think there was some delay.</b></p> <p>13 Q. But at some point in the early '90s 14 this document was a document that was authored 15 and updated by Palmetto?</p> <p>16 <b>A. It was actually Blue Cross/Blue Shield 17 before that.</b></p> <p>18 Q. Fair enough.</p> <p>19 <b>A. And became Palmetto.</b></p> <p>20 Q. Do you know about when it became 21 Palmetto? I'm not trying to pin you to any 22 particular date.</p>	<p style="text-align: right;">33</p> <p>1 <b>one document that I saw that we worked on 2 together and I'm not sure if it was shared at 3 that time or what point in time it was actually 4 shared but it was our procedure to collaborate 5 with each other on final drug fees developed.</b></p> <p>6 Q. And why were you trying to do that?</p> <p>7 <b>A. To standardize nationally.</b></p> <p>8 Q. By standardize nationally, you mean 9 making sure that the DMERC's were doing -- were 10 setting fee payments consistently?</p> <p>11 <b>A. Yes. Or let me back up, actually to 12 make sure that the fees -- the drug fees are 13 national, there's not one fee for one state, you 14 know, they shouldn't differ among the states for 15 DMERC so our goal was to make sure that one 16 contractor did not establish a fee different from 17 another.</b></p> <p>18 Q. Right, because all the methodologies 19 for setting fees should have been the same across 20 the DMERC's, correct, the governing -- the 21 governing statute at least as of 1998 required 22 them to determine to pay the lowest -- the</p>

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<p style="text-align: right;">34</p> <p>1 generic Medicare appropriate drugs to pay the 2 lower of the median of the generic AWP's or a 3 brand name AWP if it was lower, right?</p> <p>4 MR. FAUCI: Objection to form.</p> <p>5 THE WITNESS: Say that again, please.</p> <p>6 BY MR. GORTNER:</p> <p>7 Q. Let's just simplify this. The payments 8 that the DMERC's or the fees that they were 9 setting for Medicare Part B drugs, for instance, 10 those should have all been the same because 11 wasn't there one statute governing the payments 12 for Part B drugs? It didn't differ by state, did 13 it?</p> <p>14 MR. FAUCI: Objection to form.</p> <p>15 THE WITNESS: Not that I'm aware of. I 16 mean, we -- each carrier I think had their own 17 policies for establishing drugs. They were never 18 -- it was never something that each individual 19 Part B contractor collaborated on but as we moved 20 into the DMERC world and began collaborating on 21 all fee schedules nationwide, we also began 22 collaborating on DMERC drugs for consistency.</p>	<p style="text-align: right;">36</p> <p>1 <b>A. Um-hum.</b> 2 Q. And in the first -- in the first 3 paragraph you write: The subject of this letter 4 references the Uniform Drug Pricing Project - 5 Action - Reply due December 1, 1999. Do you see 6 that?</p> <p>7 <b>A. Um-hum.</b> 8 Q. What is this Uniform Drug Pricing 9 Project?</p> <p>10 <b>A. I don't recall the actual content of</b> 11 <b>the CMS request but they were trying to find out</b> 12 <b>what differences existed between different</b> 13 <b>contractors and their fee calculation practices.</b></p> <p>14 Q. What -- did the title of Uniform Drug 15 Pricing Project suggest to you that they were 16 interested in uniform drug pricing?</p> <p>17 <b>A. Yes.</b> 18 Q. And then on that same first page of the 19 December 1999 letter under a heading of 1, 20 there's a Question Number 1: How do you 21 determine AWP? What references do you use and how 22 do you get them?</p>
<p style="text-align: right;">35</p> <p>1 BY MR. GORTNER:</p> <p>2 Q. But that was a concern that had been 3 voiced at some point in the 1990s, right, the OIG 4 had written reports expressing concern that 5 DMERC's were not setting the same payment rates 6 for certain drugs; isn't that right?</p> <p>7 MR. FAUCI: Objection to the form.</p> <p>8 THE WITNESS: I can't recall exactly. I 9 know there were a lot of OIG reports and 10 everything but most of our work was driven from 11 CMS change requests.</p> <p>12 BY MR. GORTNER:</p> <p>13 Q. Let's take a look at this document, 14 Roxane Exhibit 42. Go to the first page of this 15 document, if you would, which is --</p> <p>16 MR. FAUCI: Are we on the first page of 17 the drug pricing procedure or the actual --</p> <p>18 BY MR. GORTNER:</p> <p>19 Q. The first page of Roxane Exhibit 42 is 20 a letter from you, Mrs. Stone, to HCFA and the 21 office of regional administrators. Do you see 22 that?</p>	<p style="text-align: right;">37</p> <p>1 You then wrote: Palmetto GBA follows 2 the desk procedures in Attachment I. Do you see 3 that?</p> <p>4 <b>A. Yes.</b> 5 Q. And you're referring -- Attachment I, 6 you're referring to this Medicare drug pricing 7 procedure?</p> <p>8 <b>A. Yes.</b> 9 Q. And so you were telling HCFA and the 10 office of regional administrators that the drug 11 pricing procedure was -- were the procedures 12 followed by Palmetto, is that right?</p> <p>13 <b>A. Yes.</b> 14 Q. And in that same response you also make 15 a reference that Palmetto is currently using 16 quarterly updates of the Redbook Windows CD. Let 17 me stop there. Is that a reference to the 18 Redbook CD's that were produced this summer?</p> <p>19 <b>A. Yes.</b> 20 Q. And then also the Drug Topics Redbook 21 monthly publication as well?</p> <p>22 <b>A. Yes.</b></p>

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<p>38</p> <p>1 Q. So you were using both the CD/ROM and 2 paper copies of these Redbooks, right?</p> <p>3 <b>A. That's correct.</b></p> <p>4 Q. Now, going back to the drug pricing 5 procedure guide on the first page which is Bates 6 labeled at the end 0880. It looks like there's 7 an entry there that the document was created on 8 December 12, 1995 and that it was updated on June 9 28th, 1999. Do you see that?</p> <p>10 <b>A. Yes.</b></p> <p>11 Q. Do you recall at some point in this 12 litigation searching for all copies of the drug 13 pricing procedure that would be available in your 14 office, either electronically or hard copy?</p> <p>15 <b>A. What was produced was everything we 16 had.</b></p> <p>17 Q. So is it your understanding that the 18 June 28th, 1999 update is the last version of it?</p> <p>19 <b>A. 1999. I don't recall for sure. I 20 mean, I haven't looked at dates that correspond 21 with updates.</b></p> <p>22 MR. FAUCI: Objection, form.</p>	<p>40</p> <p>1 or mailed out to providers, for instance?</p> <p>2 <b>A. No, no, these were internal.</b></p> <p>3 Q. Internal to Palmetto and any other 4 DMERC you may share it with?</p> <p>5 <b>A. True. We could possibly share it with 6 the other DMERC's. I don't know to what extent 7 we did share with the other DMERC's.</b></p> <p>8 Q. And obviously you shared it with HCFA 9 and regional offices?</p> <p>10 <b>A. Right.</b></p> <p>11 Q. I wanted to draw your attention to the 12 second page of this document Bates labeled 0881. 13 And under the heading Step 2 it says: Use 14 generics. There is a paragraph entry at the very 15 bottom that reads: To determine if a drug is 16 generic or brand, look at the bold upper-case 17 name of the drug. If there is another name for 18 the drug immediately below it in lower-case 19 letters, paren, the generic name, close paren, 20 the entries following are generally brands. If 21 there is no lower-case drug name immediately 22 below the boldface upper-case name, the boldface</p>
<p>39</p> <p>1 BY MR. GORTNER:</p> <p>2 Q. Okay. Well, when you were talking 3 earlier about looking at your procedures with 4 respect to the declaration you submitted in this 5 case, is this the type of document or is this the 6 actual document that you reviewed?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. Was this document kept internally or 9 did you put it up on a Web site?</p> <p>10 <b>A. I don't recall during this particular 11 time. I want to think it was probably hard copy 12 or kept on our network. Of course with 13 technology and change, now, today, they are on -- 14 you know, they are available on a desktop.</b></p> <p>15 Q. Have you looked at the -- is it still 16 called drug pricing procedure or does it have a 17 different name?</p> <p>18 <b>A. I don't recall the exact name.</b></p> <p>19 Q. How about in the 1999 to 2004 time 20 period, do you know one way or the other whether 21 this document was publicly available? What I 22 mean by that, was it published on your Web site</p>	<p>41</p> <p>1 upper-case name is the generic name and all 2 entries below are generics. In either case, if 3 an entry below the drug name refers to another 4 page, that entry would be for a brand name.</p> <p>5 Let me just stop there. Now, this -- 6 in the drug pricing procedure manual used by 7 Palmetto, this describes how to distinguish 8 between generics and brands, doesn't it?</p> <p>9 <b>A. Yes.</b></p> <p>10 Q. Did you ever implement this criteria in 11 classifying drugs as generic or brand?</p> <p>12 MR. FAUCI: Objet to form.</p> <p>13 THE WITNESS: Repeat that, please.</p> <p>14 BY MR. GORTNER:</p> <p>15 Q. Did Palmetto ever implement this 16 criteria in classifying drugs as generic or 17 brands?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. And can you tell me when they used this 20 criteria?</p> <p>21 <b>A. This looks like it's in reference to 22 the hard copy manuals the way it is written.</b></p>

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<p style="text-align: right;">42</p> <p>1 Q. When you mean by hard copy manuals you 2 mean --</p> <p>3 <b>A. The Redbook, the hard copy monthlies.</b></p> <p>4 Q. So when they look to the paper version, 5 they would use this criteria for classifying a 6 drug as a generic or a brand, is that right?</p> <p>7 <b>A. That's right.</b></p> <p>8 Q. Now, that's a different criteria than 9 what you said Palmetto used with respect to 10 NovaPlus Ipratropium Bromide in your declaration; 11 isn't that right?</p> <p>12 MR. FAUCI: Objection to form.</p> <p>13 BY MR. GORTNER:</p> <p>14 Q. And I'll refer you specifically to 15 Paragraph 8 of your declaration if that helps you 16 on Page 3.</p> <p>17 <b>A. Here it is making reference to how they 18 are defined on the CD in 8. There are two 19 different names on the CD and if they differed, 20 then that name was considered branded product.</b></p> <p>21 Q. My question was: That criteria, 22 whether the name is different than -- let me ask</p>	<p style="text-align: right;">44</p> <p>1 marked for identification.)</p> <p>2 BY MR. GORTNER:</p> <p>3 Q. And I'm going to hand you what's been 4 marked as Roxane 253. I'll represent to you it's 5 an excerpt of the 2000 annual Redbook that has in 6 the middle and the right column the listings for 7 Ipratropium Bromide just to orient you, Mrs. 8 Stone. Let me know if you locate the entries for 9 Ipratropium Bromide in there.</p> <p>10 <b>A. Yes, I have them.</b></p> <p>11 Q. Okay. Now, referring to this criteria 12 that's listed in the Palmetto drug pricing 13 procedure, the document we were looking at a 14 moment ago, that in a nutshell was referring to 15 whether the product was -- whether it had a 16 capitalized name and then a smaller cap name 17 underneath it. And I'm simplifying that, that 18 statement, just to orientate you to this 19 document, okay? So, for instance, if you look on 20 the far right column of the Roxane 253, you'll 21 see that there's an entry there for Ipratropium 22 Bromide Hydrous. Do you see that, Medisca?</p>
<p style="text-align: right;">43</p> <p>1 you to stop there. What are you referring to?</p> <p>2 <b>A. There is a product name or a generic 3 name of a drug such as Ipratropium Bromide. If 4 anything is added to or differentiates from 5 Ipratropium Bromide, it is considered branded.</b></p> <p>6 Q. But that applies to the Redbook CD's, 7 if you're looking at the Redbook CD's, is that 8 what you're saying?</p> <p>9 MR. FAUCI: Objection to form.</p> <p>10 THE WITNESS: I would have to see the 11 situation in the hard copy because I haven't, you 12 know, really looked at every situation.</p> <p>13 BY MR. GORTNER:</p> <p>14 Q. Okay. Let's --</p> <p>15 <b>A. Specifically NovaPlus, I don't think 16 I've seen it in the hard copy to say how it's 17 listed to confirm that.</b></p> <p>18 Q. Okay. Well, let's take a look at a 19 hard copy. Let's mark this as Roxane 253.</p> <p>20 MR. GORTNER: This is 253, counsel. 21 (Exhibit Roxane 253, Document entitled 22 Redbook 2000 Drug Topics, with attachments, was</p>	<p style="text-align: right;">45</p> <p>1 <b>A. Um-hum.</b></p> <p>2 Q. And looking at the drug pricing 3 criteria, there is a boldface upper-case name, 4 right, that reads Ipratropium Bromide Hydrous, 5 Medisca, do you see that?</p> <p>6 <b>A. Right.</b></p> <p>7 Q. And then it says: If there's another 8 drug immediately below it in lower-case, parens, 9 the generic name, the entry is generally a brand. 10 You see there's a lower-case Ipratropium Bromide, 11 the generic name underneath it?</p> <p>12 <b>A. Um-hum.</b></p> <p>13 Q. Do you see that? So would that -- 14 using that drug pricing criteria, that would lead 15 you to believe that that product would be 16 generally a brand, is that right?</p> <p>17 <b>A. Yes.</b></p> <p>18 Q. And then directly above it you see the 19 Roxane entries, there are three NDC's there?</p> <p>20 <b>A. Yes.</b></p> <p>21 Q. And in that instance there's not a bold 22 upper-case name followed by the lower-case</p>

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<p style="text-align: right;">46</p> <p>1 generic entry underneath it, right?</p> <p>2     <b>A. That's correct.</b></p> <p>3     Q. And that would -- under the criteria of</p> <p>4     Palmetto's desk pricing procedure, that would</p> <p>5     lead you to believe that those entries would be</p> <p>6     generic drugs, right?</p> <p>7     <b>A. Looking at this, yes.</b></p> <p>8     Q. Okay. Let's now look at another hard</p> <p>9     copy of Redbook. Let's mark this Roxane Exhibit</p> <p>10    254.</p> <p>11    (Exhibit Roxane 254, Document entitled</p> <p>12    Redbook 2001 Drug Topics, with attachments, was</p> <p>13    marked for identification.)</p> <p>14    <b>BY MR. GORTNER:</b></p> <p>15    Q. This is just the next year, the 2001</p> <p>16    annual update of the Redbook. And I will turn to</p> <p>17    the right page for Ipratropium Bromide which</p> <p>18    begins midway on the left-hand column.</p> <p>19    <b>MR. GORTNER:</b> Counsel, this is 254.</p> <p>20    <b>BY MR. GORTNER:</b></p> <p>21    Q. And if you look in the middle of what</p> <p>22    we've marked as Roxane 254, the 2001 angle</p>	<p style="text-align: right;">48</p> <p>1     <b>we were also using CD's.</b></p> <p>2     Q. I understand that. We'll talk about</p> <p>3     that in a moment. I'm just saying based upon the</p> <p>4     paper copies, all those entries would be</p> <p>5     considered generic, wouldn't they?</p> <p>6     <b>A. Yes.</b></p> <p>7     Q. Now, the earlier question I asked you,</p> <p>8     which was whether the methodology that Palmetto</p> <p>9     used differed from CD's to hard copies. This is</p> <p>10    a different methodology, isn't it, than what you</p> <p>11    were using for the CD's?</p> <p>12    <b>A. If you note --</b></p> <p>13    <b>MR. FAUCI:</b> Objection to form.</p> <p>14    <b>THE WITNESS:</b> If you note in our</p> <p>15    procedure it says, let's see, lower-case entries</p> <p>16    are generally brands and when we were using the</p> <p>17    CD's, I think that is when we became aware of</p> <p>18    branded generics but that's not reflected in the</p> <p>19    procedure.</p> <p>20    <b>BY MR. GORTNER:</b></p> <p>21    Q. Okay. My question is just that the</p> <p>22    reflected procedure there in the Palmetto drug</p>
<p style="text-align: right;">47</p> <p>1 Redbook, in the middle column on Page 368 do you</p> <p>2 see again there's that Ipratropium Bromide</p> <p>3 Hydrous that has the bold upper-case all caps</p> <p>4 name, smaller generic name underneath it, do you</p> <p>5 see that?</p> <p>6     <b>A. Um-hum.</b></p> <p>7     Q. That same entry that would lead you to</p> <p>8 believe it was a brand, correct?</p> <p>9     <b>A. That is correct.</b></p> <p>10    Q. And then above you can see there are</p> <p>11 now six entries under the Roxane drug, do you see</p> <p>12 that? There are three top entries that have</p> <p>13 NDC's 00054-8402 and then there are the bottom</p> <p>14 three NDC's that begin with the 0054-8404. Do</p> <p>15 you see that, six total?</p> <p>16     <b>A. Yes.</b></p> <p>17     Q. And all of those, as was the case with</p> <p>18 the NDC's we looked at in the 2000 Redbook,</p> <p>19 they're not underneath an entry that has a name</p> <p>20 in all bold caps with the lower-case generic name</p> <p>21 underneath, right?</p> <p>22     <b>A. That is correct, but during this time</b></p>	<p style="text-align: right;">49</p> <p>1 pricing procedure is looking at whether a drug is</p> <p>2 capitalized and boldfaced with a lower-case</p> <p>3 generic name under it and that's the criteria you</p> <p>4 were using at least for hard copies to determine</p> <p>5 whether a drug was generic or brand.</p> <p>6     <b>A. Yes.</b></p> <p>7     <b>MR. FAUCI:</b> Objection to form.</p> <p>8     <b>BY MR. GORTNER:</b></p> <p>9     Q. Now, I understand that when you went to</p> <p>10 the Redbook CD's, the Redbook CD's had a</p> <p>11 different way of listing the products, which</p> <p>12 we'll talk about in a moment, is that fair?</p> <p>13     <b>A. Yes.</b></p> <p>14     Q. And based upon when you would be</p> <p>15 looking at the Redbook CD's, you applied a</p> <p>16 different criteria than what's in that drug</p> <p>17 pricing procedure manual, you looked to whether</p> <p>18 the product had some name in addition or</p> <p>19 different than the generic name, am I stating</p> <p>20 that fairly?</p> <p>21     <b>MR. FAUCI:</b> Objection to form.</p> <p>22     <b>THE WITNESS:</b> Yes.</p>

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<p>1                    BY MR. GORTNER:</p> <p>2        Q. Okay. Well, let's have a look --</p> <p>3        actually, why don't we take a quick break off the</p> <p>4        record if you would like, we'll take a real quick</p> <p>5        one this time today, Jeff, and then we'll come</p> <p>6        back. Thanks.</p> <p>7        VIDEO TECHNICIAN: This concludes</p> <p>8        Videotape Number 1 in the videotape deposition of</p> <p>9        Robin Stone, 30(b)(1) and 30(b)(6)</p> <p>10      representative. The time is approximately 12:53</p> <p>11      PM. We are now off the record.</p> <p>12      (A recess transpired.)</p> <p>13      VIDEO TECHNICIAN: We are now back on</p> <p>14      the record. Today's date is October 14, 2009.</p> <p>15      The time is 1:02 PM. This is Tape Number 2 in</p> <p>16      the videotape deposition of Robin Stone, 30(b)(1)</p> <p>17      and 30(b)(6) representative of Palmetto DMERC.</p> <p>18      BY MR. GORTNER:</p> <p>19      Q. Okay, Mrs. Stone, going back to the</p> <p>20      drug pricing procedure I had marked as Roxane</p> <p>21      Exhibit 42 and in particular that section at the</p> <p>22      bottom there that indicates how to distinguish</p>	<p>50</p> <p>1        <b>them.</b></p> <p>2        Q. But you knew that that was an available</p> <p>3        option to you, that if Palmetto was unsure</p> <p>4        whether a drug should be classified as a generic</p> <p>5        or brand, it could turn to the Physician's Desk</p> <p>6        Reference, it could turn to the drug company,</p> <p>7        call up the drug company and ask it or it could</p> <p>8        call Redbook as well and get clarification, isn't</p> <p>9        that right?</p> <p>10      <b>A. Yes.</b></p> <p>11      MR. FAUCI: Objection to form.</p> <p>12      BY MR. GORTNER:</p> <p>13      Q. You don't have any recollection of ever</p> <p>14      doing that with respect to a generic or brand</p> <p>15      classification?</p> <p>16      <b>A. Not -- I don't recall a specific</b></p> <p>17      <b>situation where that may have occurred.</b></p> <p>18      Q. And what's your understanding of why</p> <p>19      the provision would include telephone the drug</p> <p>20      company as an option to determine whether a drug</p> <p>21      was generic or brand?</p> <p>22      <b>A. I don't recall why. Like I said, I</b></p>
<p>51</p> <p>1        between generic and brands. There's a carryover</p> <p>2        sentence at the bottom of Page 2 of the actual</p> <p>3        drug pricing document, from 2 to 3, that says:</p> <p>4        If there is a question as to whether a drug is a</p> <p>5        brand or generic, consult the PDR, which I</p> <p>6        imagine is the Physicians Desk Reference,</p> <p>7        Generics, telephone the drug company or Redbook</p> <p>8        itself and it gives an 800 number for Redbook.</p> <p>9        Do you recall ever consulting any of</p> <p>10      those potential sources to help determine whether</p> <p>11      a drug was a generic or a brand?</p> <p>12      <b>A. I don't recall specifically looking for</b></p> <p>13      <b>generic or brand in the PDR. I know they've used</b></p> <p>14      <b>reference to the PDR and I can't recall the</b></p> <p>15      <b>context of that particular sentence. I know they</b></p> <p>16      <b>used -- they would consult with medical directors</b></p> <p>17      <b>and nurses occasionally first and then refer to</b></p> <p>18      <b>other sources but I don't recall if PDR or if a</b></p> <p>19      <b>telephone call was made to the drug company or</b></p> <p>20      <b>Redbook specifically on any occasion. I mean, we</b></p> <p>21      <b>have called Redbook but I don't know in what</b></p> <p>22      <b>context or what content we would have contacted</b></p>	<p>51</p> <p>1        <b>don't recall why that sentence was added.</b></p> <p>2        Q. Is that something that you as someone</p> <p>3        in charge for a period of time of supervising</p> <p>4        these arrays and these classifications, is</p> <p>5        telephoning a drug company something that you</p> <p>6        would consider to be helpful in determining</p> <p>7        whether a drug was a generic or a brand?</p> <p>8        <b>A. Probably. I mean, you know, if that</b></p> <p>9        <b>came up to question, you know, to determine it.</b></p> <p>10      <b>Like I said, though, I don't know if we ever</b></p> <p>11      <b>would have had a reason to.</b></p> <p>12      Q. Do you recall ever looking at other</p> <p>13      compendium, like the First DataBank blue book,</p> <p>14      for instance, are you familiar with that</p> <p>15      compendia?</p> <p>16      <b>A. A little bit. Usually we refer to it</b></p> <p>17      <b>if we couldn't find it in Redbook.</b></p> <p>18      Q. You're aware, though, that nothing</p> <p>19      limited you to just the Redbook, is that right?</p> <p>20      MR. FAUCI: Objection to form.</p> <p>21      THE WITNESS: I can't recall the</p> <p>22      details in the CMS IOM. I think they just listed</p>

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Palmetto DMERC (Robin K. Stone)  
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15 (Pages 54 to 57)

<p>54</p> <p>1 sources that we could use. 2 BY MR. GORTNER: 3 Q. Would it surprise you that they listed 4 the First DataBank blue book as a source? 5 A. I think they did list that in there 6 and, like I said, it was our policy that if we 7 didn't find it in Redbook, then we would refer to 8 Medi-Span. 9 Q. Let me actually repeat the question 10 because we talked over each other just for a 11 moment there. Were you aware that the HCFA 12 program memorandum directed to you with respect 13 to drug pricing allowed you to consider sources 14 such as First DataBank blue book? 15 A. Yes. 16 Q. Were you also aware that you could 17 consult sources like Medi-Span? 18 A. Yes. 19 Q. You could look to those compendia for 20 AWP prices; isn't that right? 21 A. Yes. 22 Q. And you could look at those compendia</p>	<p>56</p> <p>1 differences and I think somewhere we, you know, 2 got into discussion as to generic versus branded 3 generic and the decision was made that if it's 4 branded at all, it is considered a brand. 5 Q. Okay. Can you explain to me more what 6 that means, just -- 7 A. That is where if the product name 8 versus the -- I don't know exactly what it's 9 called, it's the drug name on the CD, if it 10 differs, then it's considered a branded generic. 11 And in that case, for example, this Ipratropium 12 Hydrous may have showed the hydrous. And then 13 the Ipratropium, even though the generic name 14 matched, the hydrous added on to it, it made it 15 branded and that's how we -- you know, if it 16 differentiated it in any way, we considered it a 17 brand because of the term branded generic. 18 Q. And how was that decision made? Can 19 you explain to me the decision-making process of 20 who made it? 21 A. I don't recall the exact decisions 22 behind it, I just recall at one point in time,</p>
<p>55</p> <p>1 and help you determine whether a drug was generic 2 or brand, right? 3 MR. FAUCI: Objection to form. 4 THE WITNESS: Yes. 5 BY MR. GORTNER: 6 Q. Do you have any recollection of ever 7 looking at other compendia to determine whether a 8 drug was a generic or a brand? 9 A. I don't recall. 10 Q. Did you know that First DataBank blue 11 book, for instance, has six different indicators 12 of whether a drug is a generic? 13 A. No, I did not. 14 Q. Did the issue of how to properly 15 classify drugs as brands or generics ever come up 16 in discussions with other DMERC representatives? 17 A. I can't recall getting into 18 conversations specifically as to, you know, 19 defining them. I know internally it had come up 20 trying to distinguish, you know, between I think 21 when we began using the generics when we were 22 looking at products versus the drug name and saw</p>	<p>57</p> <p>1 you know, we always saw things as either branded 2 or generic and then branded generic got thrown 3 in. And the decision was if it had a brand -- if 4 it was a brand of generic, thereby the names 5 differentiating it, we classified it as brand. 6 Q. When you say we, you mean Palmetto 7 internally? 8 A. Palmetto, yes. 9 Q. So what happened was that internally 10 the individuals responsible for making policy 11 decisions at Palmetto made a determination that 12 if a product name had the generic name in its 13 title and something additional, you would 14 classify that as a brand for purposes of the 15 arrays? 16 A. Yes. 17 MR. FAUCI: Objection to form. 18 BY MR. GORTNER: 19 Q. And that criteria was developed 20 internally by Palmetto? 21 MR. FAUCI: Objection to form. 22 THE WITNESS: As far as I can recall it</p>

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16 (Pages 58 to 61)

<p>58</p> <p>1 was an internal policy. I don't know if it was, 2 you know, made with collaboration with other 3 contractors or carriers or not.</p> <p>4 BY MR. GORTNER:</p> <p>5 Q. Do you know who would have been 6 involved in that decision-making process?</p> <p>7 <b>A. Probably either nurses by, you know, my 8 direct report and, you know, sometimes, I don't 9 know if this particular instance would have been 10 something that we would have consulted CMS on or 11 not, I don't know.</b></p> <p>12 Q. Who's your direct report?</p> <p>13 <b>A. Carol Courtney at that time.</b></p> <p>14 Q. What was her job duty?</p> <p>15 <b>A. She was my manager at one point and 16 director at another.</b></p> <p>17 Q. But you weren't involved in that 18 decision-making process?</p> <p>19 <b>A. We would have sat down and discussed 20 it, yes.</b></p> <p>21 Q. Do you have a specific recollection of 22 being involved in that decision?</p>	<p>60</p> <p>1 BY MR. GORTNER:</p> <p>2 Q. Is it possible that it would have been 3 a decision that was made within Palmetto and 4 implemented verbally and not written down in some 5 manual or some drug procedure guide?</p> <p>6 <b>A. That is possible due to the constant 7 change that we're up against.</b></p> <p>8 Q. Now, in practice from the time period 9 of approximately 2000, 2004, that's the time 10 frame I want to focus on because that's the time 11 period when the NovaPlus Ipratropium Bromide was 12 in the arrays approximately. Palmetto looked 13 only to the Redbook publishing compendia to 14 obtain AWP's, is that right?</p> <p>15 <b>A. 2000 and 2004. I want to say yes but 16 I'm not 100 percent positive. I don't recall 17 using Medi-Span or First DataBank or whatever for 18 DMERC drugs at that point. I don't know that the 19 other carriers did either.</b></p> <p>20 Q. And I'll represent to you of the arrays 21 that we have from that time period, 2000 and 22 2004, the indications on the arrays uniformly</p>
<p>59</p> <p>1 <b>A. I remember, you know, partially Pat 2 tossing it around when we found out that there 3 were branded generics. I don't recall when or, 4 you know, all the details but whenever decisions 5 were made we would usually consult medical -- our 6 medical staff and others, you know, to just see 7 if they're on the right track.</b></p> <p>8 Q. Who was tossing it around that you 9 mentioned?</p> <p>10 <b>A. Well, it would have been within our 11 department and we would have probably consulted 12 with medical staff and possibly CMS. I don't 13 recall if that topic was, you know, directly 14 mentioned to CMS or not.</b></p> <p>15 Q. And did this decision that you're 16 talking about in terms of categorizing a drug 17 that would have a generic name in its title as 18 well as something in addition as a brand, was 19 that policy memorialized in a document anywhere?</p> <p>20 MR. FAUCI: Objection to form.</p> <p>21 THE WITNESS: I'm not sure. I'm not 22 sure.</p>	<p>61</p> <p>1 indicate that the pricing sources are, in fact, 2 from Redbook.</p> <p>3 <b>A. I would say that that's probably true.</b></p> <p>4 Again, like I mentioned previously, if there 5 wasn't a source available, we may have referred 6 to Medi-Span or First DataBank if we had that 7 source, I can't remember, but it seems like we 8 had stopped that expense at some point because it 9 was rarely used.</p> <p>10 Q. Now, with respect to using Redbook, was 11 there an internal decision at some point in time 12 to rely on the Redbook compendia for prices and 13 not other compendia during this 2000, 2004 time 14 period?</p> <p>15 <b>A. Say that again, please.</b></p> <p>16 Q. Was there a decision that was made at 17 Palmetto at some point to use either principally 18 or exclusively the Redbook compendia rather than 19 other compendia for creating the arrays?</p> <p>20 MR. FAUCI: Object to the form.</p> <p>21 THE WITNESS: You know, I don't know 22 what -- what or why we just used Redbook. At</p>

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17 (Pages 62 to 65)

<p>62</p> <p>1 that time, like I said, on DMERC we collaborated 2 with for DMERC so I don't know if that had any 3 play in it or not.</p> <p>4 BY MR. GORTNER:</p> <p>5 Q. But would your expectation be that 6 either Palmetto itself or the other DMERC's in 7 conjunction decided to use Redbook for their 8 arrays rather than some other compendia?</p> <p>9 <b>A. Probably. I mean, we used Redbook, I'm 10 sure it was for a reason.</b></p> <p>11 Q. Do you know the reason?</p> <p>12 <b>A. Probably because we had to pick, you 13 know, the one that we were most familiar with 14 because you can't sit there and go through and 15 use all sources, you know, every time because we 16 were on a time frame. It was a lot of work.</b></p> <p>17 Q. A lot of time pressures to create the 18 arrays?</p> <p>19 <b>A. Yeah.</b></p> <p>20 Q. You also indicated that Palmetto 21 transitioned at various times to different types 22 of Redbooks, that sometimes you were using the</p>	<p>64</p> <p>1 Palmetto DMERC, and I'll say or outside of HCFA 2 CMS or the other DMERC's, know which particular 3 format of Redbook you were using to create 4 pricing arrays?</p> <p>5 MR. FAUCI: Objection to form.</p> <p>6 THE WITNESS: Outside?</p> <p>7 BY MR. GORTNER:</p> <p>8 Q. Yeah.</p> <p>9 <b>A. Of CMS or Palmetto GBA? I'm not sure. 10 For some reason I want to think that there may 11 have been some type of publication that may have 12 addressed that but I'm not positive.</b></p> <p>13 Q. You're not aware sitting here today of 14 any publication that said we're using the Redbook 15 CD/ROM rather than the annual update, for 16 instance?</p> <p>17 <b>A. Probably not, but I'm not positive.</b></p> <p>18 Q. How would you find that out?</p> <p>19 <b>A. You'd have to do some extensive search 20 through old advisories but I would think that if 21 it was published, it would have been published in 22 any of our drug fee schedule publications.</b></p>
<p>63</p> <p>1 annual Redbook and then you started using a 2 CD/ROM and then at one point I think you went to 3 an Internet-based Redbook. Do you generally 4 recall that?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. And how were those decisions made? How 7 were decisions made to use different types of 8 Redbook, in some cases electronic, in some cases 9 paper copies?</p> <p>10 <b>A. Well, initially I don't think we were 11 aware even if it was available in CD/ROM so of 12 course it started out hard copy. Then with 13 technology, as anything changes, we moved towards 14 the newer technology and used the CD/ROM's. In 15 that case I think the only time we used the hard 16 copy is if it had the drug that had a more 17 current AWP.</b></p> <p>18 Q. So there was a convenience factor in 19 switching to the electronic version versus the 20 paper copy?</p> <p>21 <b>A. I'm sure that came into play.</b></p> <p>22 Q. Now, would someone outside of the</p>	<p>65</p> <p>1 Q. And what was the intended audience, if 2 you know, of those publications? Was that so the 3 providers could see what they were going to get 4 paid for a particular drug?</p> <p>5 MR. FAUCI: Objection to form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. GORTNER:</p> <p>8 Q. And were those advisories ever mailed 9 to providers directly or how were they made 10 available?</p> <p>11 <b>A. I'm not real sure, I wasn't in that 12 department. You know, I want to think that at 13 one time they mailed them. As with technology 14 they probably pushed them through e-mail or 15 whatever they use but I don't work in that 16 department.</b></p> <p>17 Q. And you're not aware, are you, of any 18 statute or any regulation that would require 19 Palmetto to use the Redbook CD/ROM versus some 20 other version of Redbook?</p> <p>21 MR. FAUCI: Objection to form.</p> <p>22 THE WITNESS: Not specifically saying</p>

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<p>66</p> <p>1 that you have to use this over this. I think 2 they gave an option.</p> <p>3 BY MR. GORTNER:</p> <p>4 Q. What kind of option?</p> <p>5 <b>A. Well, I'm just trying to think back in the old carrier's manual. I know it makes reference to them and I think it just says like Redbook Medi-Span.</b></p> <p>6 Q. So as far as you knew, you had 7 discretion to use any version of Redbook that you 8 thought was appropriate, right?</p> <p>9 <b>A. As far as I know, yes.</b></p> <p>10 Q. And as far as you knew, Palmetto had 11 discretion to use any publishing compendia like 12 Medi-Span or First DataBank if they thought it 13 was appropriate, right?</p> <p>14 <b>A. Yes.</b></p> <p>15 Q. Okay, turning to your declaration, 16 which is the exhibit there to your left that we 17 marked earlier as Roxane 252. And in particular 18 I want to focus again on Paragraph 8 of your 19 declaration.</p>	<p>68</p> <p>1 MR. FAUCI: Objection to form. 2 THE WITNESS: Yes. 3 BY MR. GORTNER:</p> <p>4 Q. Let's take a look at some of the 5 Redbook CD/ROM printouts. And what I'd like to 6 do is mark this as Roxane Exhibit 255. 7 (Exhibit Roxane 255, Document entitled 8 DMERC Medication Pricing, with attachments, was 9 marked for identification.)</p> <p>10 BY MR. GORTNER:</p> <p>11 Q. It's in two different sheets but we'll 12 just start with the top one. And I'll represent 13 to you that these are some additional documents 14 that were produced by Miss Helton from the Cigna 15 carrier. And we haven't had a chance to talk to 16 her yet about these documents but they appear to 17 be a collection if you flip through, even the 18 first one that's marked there, of the array and 19 then several pages back you'll see that she's 20 including printouts from the Redbook CD/ROM's. 21 One is a product information screening that lists 22 products and then one is a screening that's</p>
<p>67</p> <p>1 MR. FAUCI: I'll just note for the 2 record that the declaration had exhibits that are 3 not made part of the record.</p> <p>4 BY MR. GORTNER:</p> <p>5 Q. And you attest to in Paragraph 8 that 6 Palmetto classified products as brands or 7 generics based on the product name, correct?</p> <p>8 <b>A. Name, yes.</b></p> <p>9 Q. And you also state that if the product 10 name differed from the chemical name, we 11 considered it a brand, right?</p> <p>12 <b>A. Right.</b></p> <p>13 Q. And is this that criteria that you're 14 talking about that was developed -- that was 15 developed internally that if the product had 16 something in addition to the chemical name, it 17 would be treated as a brand?</p> <p>18 <b>A. Yes.</b></p> <p>19 MR. FAUCI: Objection to form.</p> <p>20 BY MR. GORTNER:</p> <p>21 Q. And that applied to when you were 22 looking at the CD/ROM's, right?</p>	<p>69</p> <p>1 called detailed product information that also 2 lists the products.</p> <p>3 And maybe I'll point you in particular 4 if you don't mind flipping to what's Bates 5 labeled at the bottom Cigna 0109. It's a little 6 bit further on in there but we'll be talking 7 about 109 through 119. If you wouldn't mind just 8 flipping through 109 to 119 quickly just to 9 familiarize yourself with those pages and I'll 10 ask you some questions.</p> <p>11 MR. FAUCI: Feel free to familiarize 12 yourself with the documents generally.</p> <p>13 THE WITNESS: Okay.</p> <p>14 BY MR. GORTNER:</p> <p>15 Q. And just so if it helps you, Mrs. 16 Stone, to clarify, what I'm really using this 17 document for is to illustrate the Redbook 18 printouts that are behind the arrays. I won't be 19 asking you any detailed questions about Cigna's 20 arrays or anything of that sort, I just -- she 21 happened to collect the printouts in a way that 22 might be easier for us to talk about them than</p>

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<p>70</p> <p>1 the ones that were on the CD's that you produced 2 to us, so in particular page Bates labeled 1 -- 3 110, 110 and 111, those sequence of pages are 4 really the ones that I'll be asking you about.</p> <p>5       <b>A. Okay.</b></p> <p>6       Q. And if you could turn to page Cigna 7 0110, the page that says Redbook for TM Windows 8 at the top, product information.</p> <p>9       <b>A. What number was it again?</b></p> <p>10      Q. I'm sorry, Cigna 0110. Are you there?</p> <p>11      <b>A. Um-hum.</b></p> <p>12      Q. And up on the right it has a release 13 October 2000 and a list of product information 14 and this appears to be product information 15 related to the various Ipratropium Bromides on 16 that Redbook CD?</p> <p>17      <b>A. Um-hum.</b></p> <p>18      Q. Do you see that? And are you familiar 19 with that screen from the Redbook CD/ROM?</p> <p>20      <b>A. Yes.</b></p> <p>21      Q. Okay. And then in the next page over 22 Bates labeled Cigna 01111 (sic) it has printouts</p>	<p>72</p> <p>1 correct?</p> <p>2       <b>A. Yes.</b></p> <p>3       Q. Okay. And then turning over to the 4 detailed product information, you can -- on the 5 screen you can click on a tab, right, that will 6 show you, for instance, for Atrovent, which is on 7 0111 at the top, it gives information about that 8 product, the product name, and it also includes 9 the generic name, doesn't it, under Ipratropium 10 Bromide?</p> <p>11      <b>A. Yes.</b></p> <p>12      Q. Let's take a look first at the name 13 Atrovent. Are you familiar with that, with that 14 product from the pricing arrays that Palmetto 15 created?</p> <p>16      <b>A. Yes.</b></p> <p>17      Q. And you classified it as a brand all 18 the time, didn't you?</p> <p>19      <b>A. Yes.</b></p> <p>20      Q. And that product name is -- Atrovent is 21 not the generic name of Ipratropium Bromide, 22 right?</p>
<p>71</p> <p>1 of what's called the detailed product information 2 for each one of these NDC's, do you see that?</p> <p>3       <b>A. Um-hum.</b></p> <p>4       Q. And you're familiar with that screen as 5 well, right?</p> <p>6       <b>A. Yes.</b></p> <p>7       Q. And these types of screens were 8 routinely on all the Redbook CD's that you used 9 to create the Palmetto arrays?</p> <p>10      <b>A. Um-hum.</b></p> <p>11      Q. You have to answer verbally. Is that a 12 yes?</p> <p>13      <b>A. Oh, yes.</b></p> <p>14      Q. Okay. And so what's on these Redbook 15 CD's that you used is first, that's a list of all 16 the product names, if you will, under the column 17 product there on Page 110?</p> <p>18      <b>A. Right.</b></p> <p>19      Q. Do you see that? And then it gives a 20 list of who the manufacturer is, the specific 21 NDC, and then AWP's and WAC's if they're 22 available are on the last two columns, is that</p>	<p>73</p> <p>1       <b>A. I'm sorry, say that again.</b></p> <p>2       Q. The product name Atrovent --</p> <p>3       <b>A. Right. Right. I'm sorry.</b></p> <p>4       Q. Let me repeat the question.</p> <p>5       <b>A. Concentration. I'm okay. Yes.</b></p> <p>6       Q. That's not -- Atrovent is not the same 7 thing as Ipratropium Bromide, the generic name, 8 right?</p> <p>9       <b>A. That's right.</b></p> <p>10      Q. And in your experience in creating 11 pricing arrays -- well, let me ask you this 12 question: Are you generally familiar in the 13 process of creating these arrays over time and 14 supervising the arrays was typical naming 15 conventions in the pharmaceutical industry for 16 generic versus brand drugs?</p> <p>17      MR. FAUCI: Objection to form.</p> <p>18      THE WITNESS: Yes.</p> <p>19      BY MR. GORTNER:</p> <p>20      Q. And the notion that Atrovent, which is 21 a name that's not the underlying generic chemical 22 compound, isn't that a typical name that you see</p>

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<p>74</p> <p>1 in brand drugs? What I mean by that is using a 2 name like Atrovent or a name like Tylenol or a 3 name like Valium which are names that don't refer 4 to the underlying generic chemical compound.</p> <p>5     <b>A. That would be true, yes.</b></p> <p>6     Q. But that's pretty standard, isn't it --</p> <p>7     <b>A. Um-hum.</b></p> <p>8     Q. -- based upon your experience?</p> <p>9     <b>A. Yes.</b></p> <p>10    Q. Now, looking at the detailed product 11 information for Atrovent, you can see that it has 12 the product name up top, it has the generic name 13 underneath there, right, Ipratropium Bromide?</p> <p>14    <b>A. Right.</b></p> <p>15    Q. Then it also has a field at the bottom 16 there that says generic, then it has in paren's 17 Y/N. Do you understand that to be is it a 18 generic, yes or no, according to Redbook?</p> <p>19    <b>A. Yes.</b></p> <p>20    Q. You see there it has an N for no, 21 right?</p> <p>22    <b>A. Yes.</b></p>	<p>76</p> <p>1 that also has a generic yes indicator from 2 Redbook, correct?</p> <p>3     <b>A. Yes.</b></p> <p>4     Q. And there are a couple other products 5 we can flip to the bottom of Page 0115 which is 6 also labeled Page 5 on the Redbook printout and 7 there's Roxane's label, Ipratropium Bromide, and 8 that was also called Ipratropium Bromide, right?</p> <p>9     <b>A. Right.</b></p> <p>10    Q. And you classified that as a generic in 11 your arrays at all times, didn't you?</p> <p>12    <b>A. Yes.</b></p> <p>13    Q. And you can see again that in the 14 generic field indicator from Redbook, that's 15 telling you that that's a generic product, 16 correct?</p> <p>17    <b>A. Correct.</b></p> <p>18    Q. And that's the same for all the other 19 Roxane labeled products there listed on Page 6 of 20 the Redbook printout. And if you skip ahead now 21 to Page 8 of the Redbook printout and Page 9, 22 which is Bates labeled Cigna 0118 and 19, there</p>
<p>75</p> <p>1     Q. Right. And you could look at that and 2 see that Redbook was telling you this is not a 3 generic product, this is a brand product, right?</p> <p>4     <b>A. Right.</b></p> <p>5     Q. Okay. Now, looking at the next entry 6 below that, there's a product from Allscripts and 7 it's called Ipratropium Bromide, right?</p> <p>8     <b>A. Um-hum.</b></p> <p>9     Q. And there the generic indicator says 10 yes, this is a generic product, correct?</p> <p>11    <b>A. Right.</b></p> <p>12    Q. And if you flip through to the next 13 page, you'll see there's an entry there for 14 Alpharma which is also called Ipratropium 15 Bromide, right?</p> <p>16    <b>A. Um-hum.</b></p> <p>17    Q. And there again Redbook is indicating 18 to you that the product is a generic product, 19 right?</p> <p>20    <b>A. That is correct.</b></p> <p>21    Q. And then on Page 01113 (sic), there's 22 an entry for Dey's Ipratropium Bromide and again</p>	<p>77</p> <p>1 you'll see the entries for the product names 2 Ipratropium Bromide and then it has a dash 3 NovaPlus, do you see that?</p> <p>4     <b>A. Um-hum.</b></p> <p>5     Q. And it has Roxane as the manufacturer, 6 correct?</p> <p>7     <b>A. Right.</b></p> <p>8     Q. And it also has the generic name listed 9 there, Ipratropium Bromide, correct?</p> <p>10    <b>A. Correct.</b></p> <p>11    Q. And then it also has another generic 12 indicator. It indicates that, yes, this is a 13 generic drug, right?</p> <p>14    <b>A. Right.</b></p> <p>15    Q. And it's the same for the other 16 NovaPlus entries below, there's a different 17 package site below that and one on Page 9 and all 18 three of those Ipratropium Bromide NovaPlus 19 entries, Redbook is telling you that it 20 classifies its product as a generic, right?</p> <p>21    <b>A. Right.</b></p> <p>22    Q. And this information was available to</p>

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21 (Pages 78 to 81)

<p>78</p> <p>1 you when you were constructing your arrays, 2 correct?</p> <p>3 <b>A. Yes.</b></p> <p>4 Q. These were on all the CD's and you 5 could see that and take that into account, 6 correct?</p> <p>7 <b>A. Um-hum.</b></p> <p>8 Q. Did you, in fact, take into account 9 Redbook's designation of the Ipratropium Bromide 10 NovaPlus products as a generic?</p> <p>11 <b>A. If I recall, this is what prompted 12 conversation that made us aware that there were 13 branded generics, which is not reflected on here, 14 and at that time it was the decision that if 15 there was any branding, it was considered a brand 16 product.</b></p> <p>17 Q. Okay. Let me make sure I understand 18 this. Was it -- you have a specific recollection 19 that it was this particular product?</p> <p>20 <b>A. No.</b></p> <p>21 Q. Oh, okay. So let me take a step back 22 because I thought you told me earlier that you</p>	<p>80</p> <p>1 <b>are -- there is something considered generic, 2 brand and branded generic.</b></p> <p>3 Q. Okay. And what was Palmetto's 4 definition of a branded generic?</p> <p>5 <b>A. That again is the product name 6 differing from the generic name and I think there 7 was probably still even a little confusion with 8 that in some cases because you may have something 9 that has hydrochloride attached to it, you know, 10 and those types of things we would take to 11 medical staff and --</b></p> <p>12 Q. Okay. So it was unclear how to 13 categorize those particular drugs that had the 14 generic name in the title and something else, is 15 that fair to say?</p> <p>16 <b>A. Yes.</b></p> <p>17 MR. FAUCI: Objection to form.</p> <p>18 BY MR. GORTNER:</p> <p>19 Q. Was the answer yes?</p> <p>20 <b>A. Yes. At one time, yes.</b></p> <p>21 Q. At one time it was unclear and you 22 weren't sure whether you should put that in as a</p>
<p>79</p> <p>1 don't know when the decision was made on branded 2 generics.</p> <p>3 <b>A. I don't know the exact timing.</b></p> <p>4 Q. So you don't know whether it had 5 anything to do with the Ipratropium Bromide 6 NovaPlus?</p> <p>7 <b>A. Right. Right.</b></p> <p>8 Q. Do you have a specific recollection, 9 though, that the decision was made before October 10 2000?</p> <p>11 <b>A. That I don't know. I don't recall the 12 timing when that was made. I would speculate 13 that when we started using the CD that we may 14 have went into, you know, questions may have come 15 up questioning whether or not because of our 16 policy that product name versus the generic name 17 differed, you know, whether or not it was 18 considered brand.</b></p> <p>19 <b>What I don't recall is where we got the 20 branded generic from. I don't know who brought 21 that to our attention of branded generic and I 22 don't recall when we started realizing that there</b></p>	<p>81</p> <p>1 generic or as a brand, is that right?</p> <p>2 <b>A. Yes.</b></p> <p>3 Q. Because it's a different -- you'd agree 4 with me it's a different name than when you have 5 exclusively a name that has nothing to do with 6 the generic chemical name like an Atrovent or a 7 Valium? In those situations in your mind is there 8 any ambiguity whether those should be classified 9 as a brand?</p> <p>10 <b>A. No.</b></p> <p>11 Q. But internally at Palmetto there was 12 ambiguity about what to do with drugs like this 13 where there is a generic chemical name in the 14 title and something else is in it as well?</p> <p>15 <b>A. Right.</b></p> <p>16 MR. FAUCI: Objection to the form.</p> <p>17 THE WITNESS: Until we learned about 18 branded generics.</p> <p>19 BY MR. GORTNER:</p> <p>20 Q. And what you meant by branded generics 21 were -- was a drug that has that particular kind 22 of title and that's your understanding of a</p>

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22 (Pages 82 to 85)

<p>82</p> <p>1 branded generic?</p> <p>2 MR. FAUCI: Object to the form.</p> <p>3 THE WITNESS: I want to think that</p> <p>4 there is some type of classification of a branded</p> <p>5 generic.</p> <p>6 BY MR. GORTNER:</p> <p>7 Q. Why, have you ever heard of a situation</p> <p>8 where there are drugs that have multiple</p> <p>9 competing products in the marketplace but they</p> <p>10 give themselves a brand name like -- ever heard</p> <p>11 of a drug called Oxycodone, for instance?</p> <p>12 <b>A. I'm not sure dealing with all the drugs</b></p> <p>13 <b>we work with every day, I'm not sure. Oxy what?</b></p> <p>14 Q. Okay. I just want to make sure that</p> <p>15 you weren't trying to make -- it doesn't sound</p> <p>16 like Palmetto was trying to make a determination</p> <p>17 of what was the pharmaceutical industry's</p> <p>18 understanding of what a branded generic is,</p> <p>19 right, that wasn't your goal --</p> <p>20 MR. FAUCI: Objection to form.</p> <p>21 BY MR. GORTNER:</p> <p>22 Q. -- was to figure out what the</p>	<p>84</p> <p>1 cases they used the PDR, may have been cases</p> <p>2 where they contacted Redbook but I don't know</p> <p>3 every, you know, situation that that might have</p> <p>4 occurred in.</p> <p>5 Q. You don't know that. But there was a</p> <p>6 process where if there were questions by the</p> <p>7 front-line staff, if you will, the staff that was</p> <p>8 actually creating the arrays and making the</p> <p>9 initial determinations, if they had questions</p> <p>10 there was a chain of command they could go up</p> <p>11 within Palmetto or they could turn to outside</p> <p>12 resources?</p> <p>13 <b>A. True.</b></p> <p>14 Q. Now, with respect to Ipratropium</p> <p>15 Bromide NovaPlus, do you have any specific</p> <p>16 recollection about the decision-making process</p> <p>17 that Palmetto went through to categorize that</p> <p>18 product as a brand or a generic?</p> <p>19 <b>A. Other than the fact that the NovaPlus</b></p> <p>20 <b>-- I don't know if they specifically, you know,</b></p> <p>21 <b>called or found out that it had a branded generic</b></p> <p>22 <b>or not, you know, or if it was just taken off</b></p>
<p>83</p> <p>1 pharmaceutical industry understands a branded</p> <p>2 generic to be, right?</p> <p>3 <b>A. We were just basing it off if it was</b></p> <p>4 <b>considered branded, it was a brand product.</b></p> <p>5 Q. I understand that. I just want to --</p> <p>6 it may be more helpful if we refer to the actual</p> <p>7 rule that you implement. And the rule that you</p> <p>8 are telling me that you implemented at some point</p> <p>9 in time was if the product had the generic</p> <p>10 chemical name in its title and any additional</p> <p>11 name, it would be -- it should have been</p> <p>12 categorized as a brand according to Palmetto's</p> <p>13 procedures, is that right?</p> <p>14 <b>A. It would depend on the differentiation</b></p> <p>15 <b>in the drug name. There may have been some --</b></p> <p>16 <b>some situation where it might have added</b></p> <p>17 <b>something that might have been considered a</b></p> <p>18 <b>diluent on the end which would differ from a</b></p> <p>19 <b>company placing what we called a branded name on</b></p> <p>20 <b>the end. And if it was questionable, the staff</b></p> <p>21 <b>would discuss it with our medical staff or</b></p> <p>22 <b>whatever that might be -- there may have been</b></p>	<p>85</p> <p>1 <b>that the product name and the additional</b></p> <p>2 <b>description differed but I would speculate that</b></p> <p>3 <b>it was based on the product name in comparison to</b></p> <p>4 <b>the generic name in this situation because</b></p> <p>5 <b>NovaPlus, I mean, as far as I know, doesn't</b></p> <p>6 <b>indicate, you know, anything that we would have</b></p> <p>7 <b>been familiar as a diluent lender such.</b></p> <p>8 Q. Okay. So -- but when you're testifying</p> <p>9 now about what actually specifically occurred</p> <p>10 with putting the Ipratropium Bromide NovaPlus</p> <p>11 into the brand arrays, you don't have a specific</p> <p>12 recollection of what either you did, if anything,</p> <p>13 related to that decision or --</p> <p>14 <b>A. If it was just following the procedure.</b></p> <p>15 Q. Right.</p> <p>16 <b>A. But I would speculate it was following</b></p> <p>17 <b>the procedure.</b></p> <p>18 MR. FAUCI: Objection to form.</p> <p>19 BY MR. GORTNER:</p> <p>20 Q. But just to use your word, you're</p> <p>21 speculating on how that actually occurred, right?</p> <p>22 MR. FAUCI: Objection to form.</p>

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23 (Pages 86 to 89)

<p style="text-align: right;">86</p> <p>1       THE WITNESS: Following, you know, the 2 -- our comparison of the product to generic name, 3 it would have been branded.</p> <p>4       BY MR. GORTNER:</p> <p>5       Q. And you said a moment ago about the 6 diluent -- are you referring to situations with a 7 product name as Ipratropium Bromide 8 hydrochloride, just to throw that name out there, 9 how would that be categorized under your 10 procedure?</p> <p>11       <b>A. It's been a long time since we've 12 actually been calculating drugs and I can't 13 recall exactly but I think that is a situation 14 that was questionable.</b></p> <p>15       Q. And what happens when it's 16 questionable?</p> <p>17       <b>A. That's when they ask -- they go to 18 medical staff to try and find determination.</b></p> <p>19       Q. But was there a rule internally at 20 Palmetto that if it had a diluent name on it, it 21 would classify it as a generic versus a brand?</p> <p>22       <b>A. I can't remember. I don't recall the</b></p>	<p style="text-align: right;">88</p> <p>1       drugs were even being submitted for reimbursement 2 to Medicare?</p> <p>3       <b>A. Nope.</b></p> <p>4       Q. Did you have any understanding whether 5 the provider community understood this drug 6 generally to be a generic or a brand?</p> <p>7       MR. FAUCI: Objection to form.</p> <p>8       THE WITNESS: No, not unless they 9 brought it to our attention and I don't recall, 10 you know, any communication to that off the top 11 of my head.</p> <p>12       BY MR. GORTNER:</p> <p>13       Q. Did you have any understanding whether 14 Roxane understood this product to be a generic or 15 a brand?</p> <p>16       <b>A. No.</b></p> <p>17       Q. And going back to that initial 18 question. So at the time that you had these 19 Redbook CD printouts that were telling you that 20 this was a generic drug, what did you do with 21 that information here in the generic code that 22 was saying yes to you?</p>
<p style="text-align: right;">87</p> <p>1       <b>final decision on that but I do know that that 2 was a situation that was questioned but I haven't 3 been calculating drugs for some time now and 4 don't look at those in comparison in how they 5 might have been used. There's a lot of drugs out 6 there, a lot of drug sources.</b></p> <p>7       Q. At the time or any time where these 8 arrays are being constructed with the Ipratropium 9 Bromide NovaPlus in them, did you know about 10 NovaPlus drugs? Was that a name you're familiar 11 with?</p> <p>12       <b>A. Not off the top of my head. I mean, we 13 didn't really pay attention to a certain company 14 or drug name. Our goal was to get in there and 15 get the work done and get the fees out.</b></p> <p>16       Q. So I take it you didn't know that these 17 were drugs that were being sold to Novation Group 18 Purchasing Organization, GPO members?</p> <p>19       <b>A. No.</b></p> <p>20       Q. You didn't know that?</p> <p>21       <b>A. No.</b></p> <p>22       Q. Did you have any idea whether these</p>	<p style="text-align: right;">89</p> <p>1       <b>A. Say that again, I'm sorry.</b></p> <p>2       Q. At the time that you had these Redbook 3 CD's and the generic field indicator in the 4 Redbook compendia is telling you that it 5 considers the Ipratropium Bromide NovaPlus drugs 6 to be a generic, what did you do, if anything, 7 with that information?</p> <p>8       <b>A. That's what prompted I think the 9 communication or the discussion regarding, you 10 know, questioning was it generic or brand because 11 it didn't match -- product and generic name did 12 not match. And as I stated before, that's when 13 we found out about branded generic and we 14 classified it as branded.</b></p> <p>15       Q. Okay. Who -- I'm just trying to 16 understand how you became informed about branded 17 generic. What does that mean?</p> <p>18       <b>A. It's a term that was -- I don't know 19 where it came from, who brought it to our 20 attention, but that's, you know, pretty much I 21 think where we started looking at the difference 22 between the product name, any difference between</b></p>

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<p style="text-align: right;">90</p> <p>1     <b>the product name and the generic name.</b></p> <p>2     Q. Okay. So some internal group at</p> <p>3     Palmetto --</p> <p>4     <b>A. I'm not sure if it was internally or</b></p> <p>5     <b>not.</b></p> <p>6     Q. You don't know who it was?</p> <p>7     <b>A. I don't know who all the players were.</b></p> <p>8     Q. You don't know who the players were but</p> <p>9     there was some internal decision-making process</p> <p>10    about what to do in these circumstances where</p> <p>11    there's a generic chemical name and something</p> <p>12    else in the title, right?</p> <p>13    <b>A. Right.</b></p> <p>14    Q. Have I got that right?</p> <p>15    <b>A. Yes.</b></p> <p>16    Q. And one of the reasons that that</p> <p>17    process occurred is because it's -- there is</p> <p>18    ambiguity with respect to that particular name,</p> <p>19    there is a generic chemical name and something</p> <p>20    added to it and based on your rule, that fell</p> <p>21    somewhere in the middle before you had this</p> <p>22    internal decision process, is that right?</p>	<p style="text-align: left;">92</p> <p>1     situation here where the compendia that you're</p> <p>2     relying upon, the Redbook compendia CD</p> <p>3     specifically classifies a drug with that</p> <p>4     particular title as a generic drug, that also</p> <p>5     created a source of potential ambiguity for how</p> <p>6     you would classify the drug, is that right?</p> <p>7     <b>A. Yes.</b></p> <p>8     Q. Now, why would that create ambiguity</p> <p>9     for you where the compendia is specifically</p> <p>10    telling you that this is a generic drug?</p> <p>11    <b>A. Because of the rule that we were</b></p> <p>12    <b>following where the product differed from the</b></p> <p>13    <b>generic name.</b></p> <p>14    Q. Okay. And in situations here where the</p> <p>15    product had the generic name and something else,</p> <p>16    it clearly didn't fit under that rule, is that</p> <p>17    right?</p> <p>18    <b>A. Right.</b></p> <p>19    MR. FAUCI: Objection to the form.</p> <p>20    BY MR. GORTNER:</p> <p>21    Q. And what that requires you to do was to</p> <p>22    figure out -- for Palmetto to figure out what it</p>
<p style="text-align: right;">91</p> <p>1     MR. FAUCI: Objection to form.</p> <p>2     THE WITNESS: Say that again, I'm</p> <p>3     sorry. I'm visualizing --</p> <p>4     BY MR. GORTNER:</p> <p>5     Q. No, let me try this -- let me try to</p> <p>6     break this into steps, it might be a little bit</p> <p>7     easier.</p> <p>8     <b>A. Okay.</b></p> <p>9     Q. I'm just trying to understand what I</p> <p>10    think you're trying to explain about how Palmetto</p> <p>11    tried to make decisions and rules about how to</p> <p>12    classify a drug like Ipratropium Bromide</p> <p>13    NovaPlus, okay?</p> <p>14    <b>A. Okay.</b></p> <p>15    Q. So let me know if I got this correct. I</p> <p>16    believe you were testifying that in situations</p> <p>17    like this where you have a drug that has both a</p> <p>18    generic name and something else added to its</p> <p>19    title, that created ambiguity at Palmetto as to</p> <p>20    whether to classify it as a brand or a generic?</p> <p>21    <b>A. Yes.</b></p> <p>22    Q. Okay. And furthermore, when you have a</p>	<p style="text-align: left;">93</p> <p>1     was going to do under these particular</p> <p>2     circumstances where the product did not clearly</p> <p>3     fit the rule, is that right?</p> <p>4     <b>A. Yeah.</b></p> <p>5     Q. Okay. And what then happened</p> <p>6     thereafter was Palmetto either internally or you</p> <p>7     don't recall, maybe in consultation with other</p> <p>8     people, came up with an additional rule which was</p> <p>9     when we run across generic products that have the</p> <p>10    generic chemical name in them and something else,</p> <p>11    we will classify them as a brand, is that right?</p> <p>12    MR. FAUCI: Objection to form.</p> <p>13    THE WITNESS: It would have -- I think</p> <p>14    they did research, you know, I can't -- I can't</p> <p>15    say, I wasn't doing it myself, they would call me</p> <p>16    as they needed. But if it didn't match and if it</p> <p>17    was questionable, then they would do research to</p> <p>18    try and make that determination.</p> <p>19    BY MR. GORTNER:</p> <p>20    Q. Okay. And this is an example of that</p> <p>21    where it didn't match those questionable, right?</p> <p>22    MR. FAUCI: Objection to form.</p>

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<p style="text-align: right;">94</p> <p>1       THE WITNESS: I can't say for certain 2 if that one would have been questionable because 3 it didn't match or that NovaPlus was considered 4 automatically branded because NovaPlus doesn't 5 make any reference to, say, another type of drug 6 or diluent, per se, but I would say that, you 7 know, it could have been questionable. I don't 8 know or recall at this time if that particular 9 drug was.</p> <p>10      BY MR. GORTNER:</p> <p>11      Q. Now, did you ever consider examining 12 the published AWP's between drugs that you 13 weren't sure were generic and a brand with drugs 14 that you knew for sure were a brand or drugs that 15 you knew for sure were generic?</p> <p>16      <b>A. There were different types of analysis 17 done but I don't recall to what extent.</b></p> <p>18      Q. Let's take a look back at the product 19 information sheet, the one that overall lists 20 them. It's on Cigna 0110, two pages back. I 21 mean, just looking at the sheet, you can see that 22 there are six Ipratropium Bromide products that</p>	<p style="text-align: right;">96</p> <p>1       same \$52.82 (sic) AWP?</p> <p>2      <b>A. Um-hum.</b></p> <p>3       MR. FAUCI: Try and answer with yes or 4 no.</p> <p>5       THE WITNESS: Yes.</p> <p>6       MR. FAUCI: Thank you.</p> <p>7       BY MR. GORTNER:</p> <p>8       Q. Okay. Was that something that you ever 9 considered, the fact that the AWP's were 10 identical between these two products and --</p> <p>11      <b>A. It was not our procedure to go in and 12 compare AWP's per se unless there was a reason, 13 you know, for us to go in and look at a specific 14 situation. This may have never been a situation 15 that, you know, anybody caught on to.</b></p> <p>16      Q. During your work supervising the array 17 and construction process and working at Palmetto 18 over the years, were you generally familiar with 19 the concept that brand AWP's for a product tended 20 to be higher than generic AWP's for product?</p> <p>21      <b>A. That --</b></p> <p>22      MR. FAUCI: Objection to form.</p>
<p style="text-align: right;">95</p> <p>1       have Roxane as a manufacturer, right?</p> <p>2      <b>A. Um-hum.</b></p> <p>3       Q. And three of them have only the 4 Ipratropium Bromide generic name, no confusion 5 there, right, that that's a generic product, 6 correct?</p> <p>7      <b>A. Right.</b></p> <p>8       Q. And three of them also have the 9 Ipratropium Bromide generic name but then have a 10 dash with NovaPlus added on the end, do you see 11 that?</p> <p>12      <b>A. Yes.</b></p> <p>13       Q. And you can see that the package sizes 14 respectively, they have identical AWP's, right?</p> <p>15       And if you look at the Roxane Ipratropium Bromide 16 25's, they have an AWP of \$44.06 and the 17 Ipratropium Bromide NovaPlus 25's have the exact 18 same \$44.06 AWP. Do you see that?</p> <p>19      <b>A. Um-hum.</b></p> <p>20       Q. The same situation with the 30's, the 21 Roxane generic product has \$52.87 and the 22 Ipratropium Bromide NovaPlus 30's have the exact</p>	<p style="text-align: right;">97</p> <p>1       THE WITNESS: That was not always true.</p> <p>2       BY MR. GORTNER:</p> <p>3       Q. Was that something you investigated and 4 studied?</p> <p>5      <b>A. We had seen situations where brand was 6 lower than generics.</b></p> <p>7       Q. But in this situation, I mean, there's 8 no doubt here that Atrovent is a brand, right?</p> <p>9      <b>A. Right.</b></p> <p>10       Q. You classified it as a brand every 11 time, correct?</p> <p>12      <b>A. Correct.</b></p> <p>13       Q. And there's no doubt looking at this 14 sheet you agree with me on Cigna 110 that every 15 single product on this sheet has the name 16 Ipratropium Bromide in it except for Atrovent; 17 isn't that right?</p> <p>18      <b>A. That's right.</b></p> <p>19       Q. Wouldn't that jump out at you that 20 there's something specifically different about 21 Atrovent compared to all the other products?</p> <p>22      MR. FAUCI: Objection to the form.</p>

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26 (Pages 98 to 101)

<p style="text-align: right;">98</p> <p>1       THE WITNESS: No, because I know there 2       were brand situations that were lower than 3       generics.</p> <p>4       BY MR. GORTNER:</p> <p>5       Q. But in this situation you agree with me 6       that the AWP for Atrovent for its 25's is \$63.72? 7       Do you see that at the top?</p> <p>8       <b>A. Um-hum.</b></p> <p>9       Q. It was significantly higher than the 10      NovaPlus AWP's, right?</p> <p>11      <b>A. Right.</b></p> <p>12      Q. And significantly higher than the 13      Roxane AWP's?</p> <p>14      <b>A. Right.</b></p> <p>15      Q. In terms of your analysis of 16      Ipratropium Bromide NovaPlus and whether it 17      should be categorized as a generic or a brand, 18      would the fact that not only Redbook but that the 19      First DataBank on all six of its generic 20      indicators identify the Ipratropium Bromide 21      NovaPlus products as a generic, would that 22      information have been useful to you in making</p>	<p style="text-align: right;">100</p> <p>1       for pricing in generic versus brand 2       classifications?</p> <p>3       <b>MR. FAUCI:</b> Objection to form.</p> <p>4       THE WITNESS: I'm not sure if I was 5       aware of that or not. I mean, it doesn't -- it 6       doesn't ring a bell, it may have been, you know, 7       I may have come across it somewhere in time but 8       didn't think anything about it.</p> <p>9       BY MR. GORTNER:</p> <p>10      Q. Do you know of any reason why the 11      Medicaid and Medicare program should be 12      classifying drugs as generics or brands 13      differently?</p> <p>14      <b>MR. FAUCI:</b> Objection to form.</p> <p>15      THE WITNESS: I'm not sure how they 16      classify or calculate their drugs.</p> <p>17      BY MR. GORTNER:</p> <p>18      Q. What about the fact that DMERC-A 19      classified its Ipratropium Bromide NovaPlus drugs 20      as generics the entire time that you were 21      classifying them as brands?</p> <p>22      <b>A. I don't recall ever seeing their actual</b></p>
<p style="text-align: right;">99</p> <p>1       your determination?</p> <p>2       <b>A. I'm sorry, say that again.</b></p> <p>3       MR. GORTNER: Can you read that back to 4       her? Or I can repeat it.</p> <p>5       (The Court Reporter read the question 6       commencing on Page 82 Line 21.)</p> <p>7       BY MR. GORTNER:</p> <p>8       Q. Let me repeat it, it will be easier.</p> <p>9       Let me repeat my question. Would the fact that 10      First DataBank on all six of its generic 11      indicators identify the Ipratropium Bromide 12      NovaPlus product as a generic, would that have 13      been useful information for you to evaluate in 14      deciding whether this drug should be classified 15      as a brand or a generic in the arrays?</p> <p>16      MR. FAUCI: Objection to the form.</p> <p>17      THE WITNESS: I'm not familiar with 18      those classifications so I'm not sure without 19      seeing them.</p> <p>20      BY MR. GORTNER:</p> <p>21      Q. Okay. Did you know that most of the 22      Medicaid programs use First DataBank blue book</p>	<p style="text-align: right;">101</p> <p>1       <b>worksheets at any given point. I don't know that</b> 2       <b>we would have even focused on that. Our goal was</b> 3       <b>to make sure our end result was the same. In</b> 4       <b>most cases our end result differed when we were</b> 5       <b>using the database and the database may have</b> 6       <b>included more current AWP information. I don't</b> 7       <b>recall ever getting any -- into discussions</b> 8       <b>whether they may have used a brand versus a</b> 9       <b>generic product differently from us.</b></p> <p>10      Q. When you say that your focus was on 11      making sure that the end result was the same, 12      what you mean by that is making sure that the fee 13      payment that's set for that J code is the same 14      across all four DMERC's, is that right?</p> <p>15      <b>A. Yes.</b></p> <p>16      Q. And in this particular instance because 17      the fee payment was at all times an Ipratropium 18      Bromide NovaPlus in the arrays was being set by 19      the median generic, it didn't matter whether the 20      product had been classified in the brand or the 21      generic arrays, is that right?</p> <p>22      MR. FAUCI: Objection to form.</p>

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<p>102</p> <p>1       THE WITNESS: Just that that's the way 2    it fell.</p> <p>3       BY MR. GORTNER:</p> <p>4       Q. I'm sorry?</p> <p>5       <b>A. That's the way the calculation came out 6    based on the sources that were available.</b></p> <p>7       Q. Okay. So --</p> <p>8       <b>A. Except the generic.</b></p> <p>9       Q. So if there were confusion at Palmetto 10   about whether Ipratropium Bromide NovaPlus should 11   be categorized as a brand or a generic, was there 12   any part of the standard procedure that would 13   have you call up another DMERC and say, what are 14   you doing with this drug, how are you classifying 15   it?</p> <p>16       <b>A. If we had unresolved differences, then 17    we usually try to work out those differences, I 18    just don't know if it ever was the result of 19    generic versus brand classification.</b></p> <p>20       Q. That's what I'm saying, how would you 21   know that there were differences in the DMERC-A's 22   classification of NovaPlus versus your</p>	<p>104</p> <p>1       Q. So it's possible that they didn't -- 2    they didn't reach the internal rule that you did 3    of if a drug has a generic name and something 4    else, we're going to classify it as a brand?</p> <p>5       <b>A. I don't know what their procedure was.</b></p> <p>6       Q. Did you speak to anyone at any other 7    DMERC about how to classify Ipratropium Bromide 8    NovaPlus?</p> <p>9       <b>A. I don't recall.</b></p> <p>10       Q. Is it a concern for you as a Palmetto 11   representative that one of your fellow DMERC's is 12   classifying a drug in the office the way that you 13   are over a period of years?</p> <p>14       MR. FAUCI: Objection to the form.</p> <p>15       THE WITNESS: We never got into that 16   discussion other than, you know, comparing our 17   fees.</p> <p>18       BY MR. GORTNER:</p> <p>19       Q. I'm not asking for discussion.</p> <p>20       <b>A. Yeah.</b></p> <p>21       Q. I'm just saying as a representative of 22   Palmetto, is that a concern for you that one</p>
<p>103</p> <p>1       classification, for instance?</p> <p>2       <b>A. I wouldn't if there wasn't a reason for 3    me to question it.</b></p> <p>4       Q. And the reason for you to question it 5    would be if the fee came out different, right?</p> <p>6       <b>A. If the fee came out different.</b></p> <p>7       Q. Okay. And the fee came out the same in 8    this instance, right?</p> <p>9       <b>A. As far as I know. I mean, I don't have 10   our comparison sheet to look at. I would have to 11   look -- go back and look and see if there was any 12   discussion or resolution for it, the final fee.</b></p> <p>13       Q. Now, as far as you know, was DMERC-A 14   following the same procedures that you were 15   following in classifying drugs or had they come 16   up with something different?</p> <p>17       MR. FAUCI: Objection to the form.</p> <p>18       THE WITNESS: If I recall -- I don't 19   know exactly what their procedure was but I do 20   recall that they were usually different from 21   everybody, for whatever reason I don't know.</p> <p>22       BY MR. GORTNER:</p>	<p>105</p> <p>1       DMERC thinks this is a generic over the course of 2    years and another DMERC is classifying it as a 3    brand over that same course of years?</p> <p>4       MR. FAUCI: Objection to the form.</p> <p>5       THE WITNESS: If I would have known, we 6    probably would have gotten into discussion or if 7    it, you know, would have stuck out or was -- you 8    know, we considered it a problem in 9    differentiating fees. But our goal, you know, we 10   -- everybody did their calculations separately 11   and then we came together at the end to resolve 12   the differences. That was our practice.</p> <p>13       BY MR. GORTNER:</p> <p>14       Q. So you wouldn't consider it a problem 15    as long as the fees came out the same?</p> <p>16       MR. FAUCI: Objection to the form.</p> <p>17       THE WITNESS: We probably would have 18   entered into some discussion as to why, you know, 19   they considered it one way and we considered it 20   another.</p> <p>21       BY MR. GORTNER:</p> <p>22       Q. Okay. Why don't we take a quick break,</p>

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<p>106</p> <p>1 okay?</p> <p>2 VIDEO TECHNICIAN: This concludes</p> <p>3 Videotape Number 2 in the videotape deposition of</p> <p>4 Robin Stone, 30(b)(1) and (30(b)(6)</p> <p>5 representative. The time is approximately 2:00</p> <p>6 PM. We are now off the record.</p> <p>7 (A recess transpired.)</p> <p>8 (Exhibit Roxane 256, Detailed Product</p> <p>9 Information sheets for Ipratropium Bromide, was</p> <p>10 marked for identification.)</p> <p>11 (Exhibit Roxane 257, Detailed Product</p> <p>12 Information sheets for Atrovent, was marked for</p> <p>13 identification.)</p> <p>14 (Exhibit Roxane 258, Detailed Product</p> <p>15 Information sheets for Ipratropium</p> <p>16 Bromide-NovaPlus, was marked for identification.)</p> <p>17 VIDEO TECHNICIAN: We are now back on</p> <p>18 the record. Today's date is October 14, 2009.</p> <p>19 The time is 2:09 PM. This is Tape Number 3 in</p> <p>20 the videotape deposition of Robin Stone, 30(b)(1)</p> <p>21 and 30(b)(6) representative of Palmetto DMERC.</p> <p>22 BY MR. GORTNER:</p>	<p>108</p> <p>1 and they certainly appear to be what they were</p> <p>2 represented. We reserve the right if we notice</p> <p>3 that there is a difference later.</p> <p>4 MR. GORTNER: Okay.</p> <p>5 THE WITNESS: Okay.</p> <p>6 BY MR. GORTNER:</p> <p>7 Q. And we can set those aside for now just</p> <p>8 to kind of keep the exhibits completely from</p> <p>9 overwhelming you.</p> <p>10 Now, I wanted to go back to your</p> <p>11 declaration and in particular on Page 3 and look</p> <p>12 at Paragraph 8 where you stated that Palmetto</p> <p>13 classified products as brands or generics based</p> <p>14 on the product name and if it differed from the</p> <p>15 chemical name you considered it a brand. And you</p> <p>16 go on to say: This was the case with NovaPlus.</p> <p>17 And you state: Because this product had the</p> <p>18 trade name NovaPlus added to the chemical name,</p> <p>19 we considered it a brand product, right? Do you</p> <p>20 see that statement?</p> <p>21 A. Yes.</p> <p>22 Q. And from what we were talking about</p>
<p>107</p> <p>1 Q. Mrs. Stone, I'm going to be handing you</p> <p>2 what we've collectively marked as Roxane Exhibits</p> <p>3 256, 257 and 258. What these are are printouts</p> <p>4 for three particular drugs that were on the</p> <p>5 Redbook CD's that you produced to us in late</p> <p>6 summer of this year. The first one, Roxane 256,</p> <p>7 I'll represent to you is the detailed product</p> <p>8 information sheet from the Redbook CD/ROM's for</p> <p>9 the Roxane label of Ipratropium Bromide. Exhibit</p> <p>10 257 is the same detailed product information</p> <p>11 sheets for Atrovent. And Roxane 258 are the</p> <p>12 detailed product information sheets for</p> <p>13 Ipratropium Bromide-NovaPlus. And again, I</p> <p>14 understand that the government has stipulated to</p> <p>15 the authenticity of these documents as coming</p> <p>16 from the Redbook CD's that you produced. I just</p> <p>17 want to have you look at them quickly and confirm</p> <p>18 that those, in fact, appear to be accurate and</p> <p>19 correct copies of the detailed product</p> <p>20 information that were on those CD's.</p> <p>21 MR. FAUCI: I'll just state on behalf</p> <p>22 of the United States I've skimmed through these</p>	<p>109</p> <p>1 earlier, that particular paragraph is not coming</p> <p>2 from a specific recollection of exactly how you</p> <p>3 classified the product or the decision-making</p> <p>4 process behind that classification, it's rather</p> <p>5 you looking at the arrays now and the procedures</p> <p>6 and reconstructing what you think likely</p> <p>7 occurred, is that a fair characterization?</p> <p>8 MR. FAUCI: Object to the form.</p> <p>9 THE WITNESS: I mean, we looked at the</p> <p>10 product name and compared it to the generic name</p> <p>11 and would for the most part, unless something,</p> <p>12 you know, made us question it, would use that as</p> <p>13 our procedure to distinguish a brand.</p> <p>14 BY MR. GORTNER:</p> <p>15 Q. What I'm saying is sitting here today</p> <p>16 or when you wrote this declaration, you didn't</p> <p>17 recall specifically what Palmetto actually did</p> <p>18 with the NovaPlus product?</p> <p>19 A. The product versus the generic name was</p> <p>20 pretty much our practice.</p> <p>21 Q. I understand that, but you don't recall</p> <p>22 specifically how that practice was applied in</p>

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<p>110</p> <p>1 this specific instance, right?</p> <p>2 <b>A. Oh. Right. I mean...</b></p> <p>3 Q. You said right?</p> <p>4 <b>A. I can't -- I mean, I can't say that</b></p> <p>5 <b>that would be true. I mean, we would have used</b></p> <p>6 <b>the brand -- the product versus generic for</b></p> <p>7 <b>NovaPlus products for Ipratropium and if there</b></p> <p>8 <b>was any reason to think that we needed to go</b></p> <p>9 <b>further and determine that, then we would.</b></p> <p>10 Q. But that's again a different rule than</p> <p>11 the rule that we saw in the drug pricing</p> <p>12 procedure manual that we went through a little</p> <p>13 bit earlier which looked at capitalization</p> <p>14 issues, right?</p> <p>15 MR. FAUCI: Object to the form.</p> <p>16 THE WITNESS: Which was specific to the</p> <p>17 book.</p> <p>18 BY MR. GORTNER:</p> <p>19 Q. Right. Okay. So what I'm saying is</p> <p>20 you had one rule that you applied to the CD/ROM</p> <p>21 and you had another rule that you applied when</p> <p>22 looking at the printed product, correct?</p>	<p>112</p> <p>1 it?</p> <p>2 <b>A. I don't recall exactly what the</b></p> <p>3 <b>specific decision was on diluents or specific</b></p> <p>4 <b>diluents. There's a lot of -- you know,</b></p> <p>5 <b>depending on the situation there are exceptions</b></p> <p>6 <b>to the rules that might have been considered.</b></p> <p>7 Q. Was the definition of a trade name</p> <p>8 something that Palmetto created on its own?</p> <p>9 MR. FAUCI: Object to the form.</p> <p>10 THE WITNESS: The trade name, I mean, a</p> <p>11 trade name, I don't know exactly where the</p> <p>12 terminology comes from. Again, trade name is</p> <p>13 just saying that, you know, there's another name</p> <p>14 added on to the generic name.</p> <p>15 BY MR. GORTNER:</p> <p>16 Q. Who would make --</p> <p>17 <b>A. Terminology.</b></p> <p>18 Q. Who would make that decision, would it</p> <p>19 be the front-line person? I don't know if</p> <p>20 there's an employee title that I should be using</p> <p>21 for the person who's actually assigning</p> <p>22 categorizations of drugs into the particular</p>
<p>111</p> <p>1 MR. FAUCI: Object to the form.</p> <p>2 THE WITNESS: Well, I mean, as far as I</p> <p>3 can recall, yes.</p> <p>4 BY MR. GORTNER:</p> <p>5 Q. Okay. Now, what's your definition or</p> <p>6 what's Palmetto's definition of a trade name?</p> <p>7 <b>A. Anything differing from the product and</b></p> <p>8 <b>the chemical name. NovaPlus added on to the</b></p> <p>9 <b>generic name would make it a trade name to us.</b></p> <p>10 Q. Well, how about a diluent? You</p> <p>11 indicated earlier that a diluent might not cause</p> <p>12 it to be classified as a brand.</p> <p>13 <b>A. And that's where I said that we would</b></p> <p>14 <b>get into the discussion of does the diluent</b></p> <p>15 <b>change the drug or is it considered part of the</b></p> <p>16 <b>chemical drug itself.</b></p> <p>17 Q. And how did you decide? What was the</p> <p>18 criteria for deciding whether it changed the name</p> <p>19 or not?</p> <p>20 <b>A. That's when we would probably get input</b></p> <p>21 <b>from the medical staff.</b></p> <p>22 Q. And what was their criteria if you know</p>	<p>113</p> <p>1 arrays.</p> <p>2 <b>A. Usually we follow the procedure and in</b></p> <p>3 <b>the case if the product name and/or the generic</b></p> <p>4 <b>name differed, it would be looked at. If it was</b></p> <p>5 <b>-- looked like it was a trade name or a brand</b></p> <p>6 <b>name, it would be treated as a brand.</b></p> <p>7 Q. But that wasn't your role at the time,</p> <p>8 though, right, 2002, 2004, you weren't the person</p> <p>9 that was actually looking at the Redbook printed</p> <p>10 version or the CD/ROM's and deciding where to put</p> <p>11 the drugs; isn't that right?</p> <p>12 <b>A. Right.</b></p> <p>13 Q. You were supervising, you were higher</p> <p>14 up, okay?</p> <p>15 <b>A. I was the lead.</b></p> <p>16 Q. That's higher up?</p> <p>17 <b>A. Yeah.</b></p> <p>18 Q. Okay. And then there were -- how many</p> <p>19 employees would be involved in the construction</p> <p>20 of this -- of this Ipratropium Bromide array,</p> <p>21 would it be one person who would do that?</p> <p>22 <b>A. I'm trying to think. Either one or two</b></p>

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<p style="text-align: right;">114</p> <p>1   <b>for DMERC, there was one specific person for Part</b> 2   <b>B.</b></p> <p>3   Q. But the one or two person for DMERC, 4   would they split up the J codes? They wouldn't 5   be duplicating the work, would they?</p> <p>6   <b>A. That's what I'm trying to think, I</b> 7   <b>can't remember if they traded off or if one</b> 8   <b>person was doing it all together at one time. I</b> 9   <b>just -- I can't remember how they were splitting</b> 10   <b>that work but I want to think one person was</b> 11   <b>doing it in any given time but they always -- we</b> 12   <b>were always cross-training people along the way.</b></p> <p>13   Q. Okay. But generally speaking there was 14   one person that would have been looking at some 15   format of the Redbook and with respect to this 16   particular -- or the particular J codes where the 17   Ipratropium Bromide NovaPlus product was in, they 18   had to make a determination is this product name 19   one that should be classified as a generic or a 20   brand according to the rule you issued in your 21   declaration, right?</p> <p>22   <b>A. Um-hum.</b></p>	<p style="text-align: right;">116</p> <p>1   NovaPlus goes to the brand or the generic array, 2   that determination holds across every subsequent 3   quarter, it's not reevaluated?</p> <p>4   <b>A. Unless there's given reason to.</b></p> <p>5   Q. You're not aware of any reason here 6   when they reevaluated it?</p> <p>7   <b>A. No.</b></p> <p>8   Q. So someone when it first showed up in 9   the array made -- according to your declaration 10   made the determination that NovaPlus was a trade 11   name and put the product in the brand portion of 12   the array?</p> <p>13   <b>A. Without seeing the first time it was</b> 14   <b>used in a calculation, I can't say, but I would</b> 15   <b>think that that would be what the case would have</b> 16   <b>been.</b></p> <p>17   Q. Okay. And my question is: How did 18   that individual determine that NovaPlus was a 19   trade name?</p> <p>20   <b>MR. FAUCI: Object to the form.</b></p> <p>21   <b>THE WITNESS: Looking at the product</b> 22   <b>compared to the generic name and if it was</b></p>
<p style="text-align: right;">115</p> <p>1   Q. Is that a yes?</p> <p>2   <b>A. Yes.</b></p> <p>3   Q. Okay. And that person then had to 4   determine whether NovaPlus was a trade name, 5   right?</p> <p>6   <b>A. Right.</b></p> <p>7   Q. And my question to you is: Do you know 8   how that person -- how did that person make a 9   determination?</p> <p>10   <b>MR. FAUCI: Object to the form.</b></p> <p>11   <b>THE WITNESS: I mean, it's probably --</b> 12   once you establish a calculation, you've got -- 13   you're using the same files from the previous 14   quarter going into the new quarter. So if it had 15   been determined prior to them calculating, they 16   wouldn't question it.</p> <p>17   <b>BY MR. GORTNER:</b></p> <p>18   Q. Okay. That's fair enough. What 19   happens here is that the first time it shows up 20   in the array, and let's say I think that's 21   October 2000, assuming that's the case, that 22   determination of whether Ipratropium Bromide</p>	<p style="text-align: right;">117</p> <p>1   questionable, it would have entered into 2   discussion for review for final determination.</p> <p>3   <b>BY MR. GORTNER:</b></p> <p>4   Q. And you don't know whether it -- that 5   product, whether it entered into review for 6   determination?</p> <p>7   <b>A. Yeah, I don't know if this particular</b> 8   <b>Ipratropium Bromide product would have prompted</b> 9   <b>that determination or if that determination would</b> 10   <b>have been made prior to that.</b></p> <p>11   Q. Okay. At what point would you have any 12   input into determining whether NovaPlus was a 13   trade name or not?</p> <p>14   <b>A. If -- I mean, if it got questioned,</b> 15   <b>they would usually come to myself or whoever was</b> 16   <b>acting, you know, their report at that time. At</b> 17   <b>one time I was DMERC only and took on Part B</b> 18   <b>later but it would just depend on who the person</b> 19   <b>was mentoring with and if they, you know, were</b> 20   <b>questionable with their mentor, then they would</b> 21   <b>come to me for a final determination.</b></p> <p>22   Q. Was there any written definition of</p>

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<p style="text-align: right;">118</p> <p>1 what a trade name is at Palmetto?</p> <p>2 <b>A. Not that I'm aware of.</b></p> <p>3 Q. Was there any written definition about</p> <p>4 when you determined that a product that has a</p> <p>5 generic -- the generic chemical name in it should</p> <p>6 not be classified as a generic?</p> <p>7 MR. FAUCI: Object to the form.</p> <p>8 THE WITNESS: I don't know per se</p> <p>9 without going through everything and looking back</p> <p>10 at everything but I don't know when that changed.</p> <p>11 BY MR. GORTNER:</p> <p>12 Q. So is it fair to say that the</p> <p>13 classification of Ipratropium Bromide NovaPlus</p> <p>14 depended on the judgment of this individual who</p> <p>15 was constructing that particular array when it</p> <p>16 first came into the Palmetto arrays?</p> <p>17 MR. FAUCI: Object to the form.</p> <p>18 THE WITNESS: Like I said before, it</p> <p>19 would depend on when the determination on the</p> <p>20 product versus the generic name, how all that</p> <p>21 rolled out as to when Ipratropium Bromide</p> <p>22 NovaPlus came in for calculation.</p>	<p style="text-align: right;">120</p> <p>1 determination whether this Ipratropium Bromide</p> <p>2 product met that rule or not?</p> <p>3 <b>A. For the first time, yes.</b></p> <p>4 Q. For the first time there's an</p> <p>5 individual at Palmetto that has to --</p> <p>6 <b>A. Say that.</b></p> <p>7 Q. -- say one of two things according to</p> <p>8 your testimony. One is that we have an</p> <p>9 established rule that when a product has a</p> <p>10 generic name in it and something more that's not</p> <p>11 a diluent, that product should be classified as a</p> <p>12 brand or if there's no such rule, it might prompt</p> <p>13 a discussion about what to do with this product,</p> <p>14 is that right?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. And in this particular case you don't</p> <p>17 know what happened?</p> <p>18 <b>A. No, none, not at that time.</b></p> <p>19 Q. Now -- and there was no written rule</p> <p>20 explaining this generic versus branded generic</p> <p>21 distinction, correct?</p> <p>22 MR. FAUCI: Object to the form.</p>
<p style="text-align: right;">119</p> <p>1 BY MR. GORTNER:</p> <p>2 Q. Okay. Well, we can look in here. We</p> <p>3 can look at the arrays and I can tell you exactly</p> <p>4 when it first shows up in the arrays if that</p> <p>5 would be helpful for you.</p> <p>6 <b>A. Well, what I'm saying, I don't know</b></p> <p>7 <b>when the rules using product versus generic name,</b></p> <p>8 <b>you know, were established as to what they were</b></p> <p>9 <b>doing that would have prompted the question for</b></p> <p>10 <b>this particular drug.</b></p> <p>11 Q. I see what you're saying. I see what</p> <p>12 you're saying. So if Palmetto's rule about</p> <p>13 establishing whether something was a generic or a</p> <p>14 branded generic under the definition of and</p> <p>15 including the generic name plus some additional</p> <p>16 term or terms, if that rule had been established</p> <p>17 before Ipratropium Bromide NovaPlus could enter</p> <p>18 the arrays, that rule would control the</p> <p>19 classification of the product?</p> <p>20 <b>A. I would say yes. There's --</b></p> <p>21 Q. But wouldn't it require the individual</p> <p>22 that's constructing the arrays to still make a</p>	<p style="text-align: right;">121</p> <p>1 THE WITNESS: I don't know off the top</p> <p>2 of my head. I mean, procedures, you know, were</p> <p>3 updated, I just -- I don't know if it was ever</p> <p>4 updated based on what I'm seeing here to say it</p> <p>5 was or wasn't.</p> <p>6 BY MR. GORTNER:</p> <p>7 Q. But it may have been more of an</p> <p>8 informal person where the person who is</p> <p>9 constructing the arrays is talking to the</p> <p>10 supervisor and you're talking to the medical</p> <p>11 director, if necessary, and that's how it</p> <p>12 generally works here, is that there's a process</p> <p>13 by which folks are talking back and forth, make</p> <p>14 these types of decisions when it's a close call?</p> <p>15 MR. FAUCI: Object to the form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. GORTNER:</p> <p>18 Q. And theoretically this same internal</p> <p>19 decision-making process has to occur at the three</p> <p>20 other DMERC's, right, each one of them has to</p> <p>21 determine at some point whether Ipratropium</p> <p>22 Bromide NovaPlus should go into a generic or a</p>

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<p>122</p> <p>1 brand array, right?</p> <p>2 <b>A. Yes.</b></p> <p>3 Q. And the four of you aren't doing this</p> <p>4 all in a concerte collective effort, right?</p> <p>5 MR. FAUCI: Object to the form.</p> <p>6 THE WITNESS: Not that I can recall to</p> <p>7 that level.</p> <p>8 BY MR. GORTNER:</p> <p>9 Q. And the outcome was, you know, DMERC-A</p> <p>10 decides under whatever their rules are, we think</p> <p>11 this product belongs in the generic array the</p> <p>12 whole time, right?</p> <p>13 <b>A. It could. I don't recall.</b></p> <p>14 Q. Now, you have CVS pharmacies down here,</p> <p>15 don't you?</p> <p>16 <b>A. Yes.</b></p> <p>17 Q. It's a big kind of retail pharmacy</p> <p>18 chain, is that right?</p> <p>19 <b>A. Um-hum. Yes.</b></p> <p>20 Q. Do you have a Walgreens down here as</p> <p>21 well? Is Walgreens --</p> <p>22 <b>A. Yes.</b></p>	<p>124</p> <p>1 Q. And why would you open discussion on</p> <p>2 it?</p> <p>3 <b>A. I don't know that I would or not, I'm</b></p> <p>4 <b>just saying that it is -- it differs and they've</b></p> <p>5 <b>put their name on it; therefore, they have</b></p> <p>6 <b>branded it with their name.</b></p> <p>7 Q. Okay. And the same would go for</p> <p>8 Walgreens if there was a product that said</p> <p>9 Ipratropium Bromide, had a dash Walgreens, that</p> <p>10 would be classified as a brand product?</p> <p>11 <b>A. Probably. I've never seen it so, you</b></p> <p>12 <b>know, it's hard to say.</b></p> <p>13 Q. But these are things that if you saw a</p> <p>14 product that said Ipratropium Bromide dash</p> <p>15 Walgreens, I mean, you -- a reasonable response</p> <p>16 in your view would be to have a discussion</p> <p>17 internally about whether that fits Palmetto's</p> <p>18 definition of a brand or a generic, correct?</p> <p>19 MR. FAUCI: Objection to the form.</p> <p>20 THE WITNESS: That might have been --</p> <p>21 prompted conversation, yes.</p> <p>22 BY MR. GORTNER:</p>
<p>123</p> <p>1 Q. Okay. I'm not sure, there's all these</p> <p>2 regional differences in pharmacies so I want to</p> <p>3 be sure. I thought I saw a CVS when I was</p> <p>4 driving in. Is CVS a trade name?</p> <p>5 MR. FAUCI: Object to the form.</p> <p>6 THE WITNESS: I would guess. They're</p> <p>7 not -- they're not called a pharmacy but...</p> <p>8 BY MR. GORTNER:</p> <p>9 Q. So if you had a product that was called</p> <p>10 Ipratropium Bromide and had a dash CVS, under</p> <p>11 your criteria you would classify that as a brand,</p> <p>12 wouldn't you, it's not a generic?</p> <p>13 <b>A. They've branded it.</b></p> <p>14 Q. I'm sorry, say that again.</p> <p>15 <b>A. They've branded it.</b></p> <p>16 Q. Under your view that's a brand product?</p> <p>17 MR. FAUCI: Object to the form.</p> <p>18 THE WITNESS: Again, we probably would</p> <p>19 open discussion on that but I would say that that</p> <p>20 would be a branded product, they've put their</p> <p>21 name on it.</p> <p>22 BY MR. GORTNER:</p>	<p>125</p> <p>1 Q. Right. Because people within Palmetto,</p> <p>2 couldn't there be reasonable disagreement when</p> <p>3 someone says, no, it's got the generic chemical</p> <p>4 name Ipratropium Bromide in the title, it's just</p> <p>5 identified in the Walgreens supplier, I don't</p> <p>6 think that's the same as the product that's</p> <p>7 called Atrovent, that would be a reasonable</p> <p>8 discussion that you could have with Palmetto,</p> <p>9 right?</p> <p>10 MR. FAUCI: Eric, are you talking about</p> <p>11 that CVS -- just for clarification, are we</p> <p>12 talking about a situation where CVS and Walgreens</p> <p>13 appears in the drug's name?</p> <p>14 MR. GORTNER: Yes.</p> <p>15 BY MR. GORTNER:</p> <p>16 Q. Let me be clear for all these questions</p> <p>17 and correct your answer if I'm not being clear.</p> <p>18 I'm assuming that the product name is -- I'm</p> <p>19 replacing NovaPlus with CVS or Walgreens so the</p> <p>20 product says Ipratropium Bromide dash CVS just as</p> <p>21 it's listed in the Redbook CD but instead of</p> <p>22 NovaPlus it has a pharmacy.</p>

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<p style="text-align: right;">126</p> <p>1     <b>A. My first response would be or thought</b>    2     <b>would be that it would be considered branded</b>    3     <b>generic.</b></p> <p>4     Q. Okay.</p> <p>5     <b>A. It could prompt additional discussion</b>    6     <b>what the outcome would have been, you know, I</b>    7     <b>don't know, I can't recall what decision went</b>    8     <b>behind NovaPlus in saying that, okay, it is a</b>    9     <b>branded generic.</b></p> <p>10    Q. My question isn't so much the ultimate      11 outcome but rather that that initial assessment      12 is something that involves ambiguity, that people      13 at Palmetto could see it differently, right?</p> <p>14    <b>A. Um-hum.</b></p> <p>15    MR. FAUCI: Object to the form.</p> <p>16    BY MR. GORTNER:</p> <p>17    Q. And in your view that wouldn't be      18 unreasonable, would it, for someone at Palmetto      19 involved with the array process to say, no, I      20 don't think Ipratropium Bromide dash Walgreens      21 should be thought of as a brand, I think it's      22 closer to a generic, a brand name like Atrovent?</p>	<p style="text-align: right;">128</p> <p>1     something that they would consider?</p> <p>2     MR. FAUCI: Object to the form.</p> <p>3     THE WITNESS: I don't know. I don't</p> <p>4     know. Unless, you know, I'm put in that position</p> <p>5     to look at that specific situation because drugs,</p> <p>6     there's many exceptions.</p> <p>7     BY MR. GORTNER:</p> <p>8     Q. But you know -- let me ask you as a</p> <p>9     consumer. When you walk into CVS and you see a</p> <p>10    product that says ibuprofen CVS and next to it</p> <p>11    there's a product named Tylenol, is there a</p> <p>12    question in your mind that the CVS ibuprofen is a</p> <p>13    generic product?</p> <p>14    MR. FAUCI: Objection to the form.</p> <p>15    That's beyond the scope of this deposition.</p> <p>16    BY MR. GORTNER:</p> <p>17    Q. You can answer the question.</p> <p>18    <b>A. You know, I don't know. I mean, I go</b>      19 <b>in, I don't usually think about it, I know what</b>      20 <b>I'm buying and I go in. I guess I've never</b>      21 <b>looked at it from over-the-counter drug</b>      22 <b>perspective.</b></p>
<p style="text-align: right;">127</p> <p>1     MR. FAUCI: Object to the form.</p> <p>2     THE WITNESS: It -- I mean, we would --</p> <p>3     it could hold discussion but, I mean, there would</p> <p>4     be research.</p> <p>5     BY MR. GORTNER:</p> <p>6     Q. And what would the research be?</p> <p>7     <b>A. Based on any input given back from the</b>      8 <b>medical director, the nurses and if we had a</b>      9 <b>pharmacy available to us, which sometimes -- a</b>      10 <b>pharmacist, you know, it would involve, you know,</b>      11 <b>different discussions with those.</b></p> <p>12    Q. But what would be the nature of -- I</p> <p>13    know you don't know specifically what they're</p> <p>14    saying on a drug-on-drug basis, I'm just trying</p> <p>15    to understand what is the retail pharmacist on</p> <p>16    staff, for instance, what's his input into this</p> <p>17    process?</p> <p>18    <b>A. Just to give his guidance.</b></p> <p>19    Q. Would you anticipate that they would</p> <p>20    look to whether a product like Ipratropium</p> <p>21    Bromide dash Walgreens, whether that product was</p> <p>22    considered generic by pharmacists, is that</p>	<p style="text-align: right;">129</p> <p>1     Q. You never thought about whether drugs</p> <p>2     that have a Costco label on them or CVS or</p> <p>3     Walgreens label, whether that's --</p> <p>4     <b>A. They're cheaper, yeah.</b></p> <p>5     Q. But you never thought about whether</p> <p>6     they were generic, they should be -- whether you</p> <p>7     think of them as a generic or a brand?</p> <p>8     <b>A. Well, NovaPlus didn't match --</b></p> <p>9     MR. FAUCI: Object to the form.</p> <p>10    THE WITNESS: NovaPlus doesn't match</p> <p>11    the manufacturer and, I mean, I don't know. I</p> <p>12    don't know.</p> <p>13    BY MR. GORTNER:</p> <p>14    Q. You don't know the answer to that?</p> <p>15    <b>A. I probably would think about it but at</b>      16 <b>the time the procedure was and the decision was</b>      17 <b>to use the product if it differed. If we saw CVS</b>      18 <b>or Walgreens, we probably would enter into a</b>      19 <b>decision and probably determine that that would</b>      20 <b>be generic. But NovaPlus, like I said, I don't</b>      21 <b>know the -- I don't know the details that went</b>      22 <b>into defining NovaPlus as a brand. I don't know</b></p>

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<p style="text-align: right;">130</p> <p>1 if, you know, that branded generic concept 2 applied to that but, you know, we had guidance to 3 do that and that's what we did.</p> <p>4 Q. Fair enough. I think what I'm trying 5 to understand is whether or not it was an 6 ironclad rule. What I think you just said --</p> <p>7 <b>A. And I can't say that that was.</b></p> <p>8 Q. Exactly. It was a subject of 9 discussion so when you have situations where a 10 generic name has something in addition to it like 11 in this case where a hypothetical CVS or 12 Walgreens.</p> <p>13 <b>A. Right.</b></p> <p>14 Q. That's a subject of discussion at 15 Palmetto, right?</p> <p>16 <b>A. Right.</b></p> <p>17 MR. FAUCI: Objection to the form.</p> <p>18 BY MR. GORTNER:</p> <p>19 Q. How about if the product was named 20 Ipratropium Bromide dash Roxane?</p> <p>21 MR. FAUCI: Object to the form.</p> <p>22 BY MR. GORTNER:</p>	<p style="text-align: right;">132</p> <p>1 else and found that out, I don't recall. 2 Q. Now, how about if the product was 3 advertised as Ipratropium Bromide dash NovaPlus, 4 this is a generic drug? That's the entire title. 5 MR. FAUCI: Objection to the form. 6 BY MR. GORTNER: 7 Q. What would you do under those 8 circumstances? 9 <b>A. It would definitely be up for 10 discussion.</b> 11 Q. But you don't know whether it would be 12 classified on that basis, a brand or a generic? 13 <b>A. I would --</b> 14 MR. FAUCI: Objection to the form. 15 THE WITNESS: I mean, I would think 16 that it's generic but... 17 BY MR. GORTNER: 18 Q. You would think it's generic. And why 19 is that? 20 <b>A. Well, going out to the site that it 21 does classify it as a generic but, again, it 22 would open up into discussion is it brand, it's</b></p>
<p style="text-align: right;">131</p> <p>1 Q. How would you classify that product? 2 <b>A. I don't know.</b> 3 Q. Would that also be a subject for 4 discussion? 5 <b>A. It would be subject for discussion 6 since Roxane also had other products in which 7 they did not add something additional to their 8 name.</b> 9 Q. And what would be the nature of the 10 discussion? 11 <b>A. Going through and determining is it 12 considered a branded generic or generic.</b> 13 Q. And you can't tell me the criteria for 14 branded generic again? 15 <b>A. I cannot recall what or where that 16 information is that defines branded generic from 17 generic.</b> 18 Q. There was some internal understanding 19 of a what a branded generic was? 20 <b>A. Or if it came from, you know, like in 21 the procedures if they contacted Redbook and 22 found that out or if they looked at something</b></p>	<p style="text-align: right;">133</p> <p>1 <b>generic.</b> 2 Q. And the sole reason for that would be 3 the presence of the term NovaPlus in the title in 4 addition to these other words? 5 <b>A. That would have --</b> 6 MR. FAUCI: Objection to the form. 7 THE WITNESS: -- caused us to question 8 it, yes, because of our knowledge of branded 9 generic sources. 10 BY MR. GORTNER: 11 Q. But if a manufacturer is telegraphing 12 to you in the title something like that, this is 13 a generic drug, that's something that would lead 14 you to believe it's a generic, right? 15 MR. FAUCI: Object to the form. 16 THE WITNESS: We probably would still 17 question it even coming from the manufacturer 18 because of the term that we were aware of being 19 branded generic. 20 BY MR. GORTNER: 21 Q. Let's take a look -- could you go back 22 to the 2001 Redbook printout. And I need to get</p>

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<p style="text-align: right;">134</p> <p>1 the --</p> <p>2 MR. FAUCI: Talking about the Redbook</p> <p>3 for CD?</p> <p>4 MR. GORTNER: No, I'm sorry, the</p> <p>5 printed version of the annual Redbook. Let me go</p> <p>6 to -- it is -- it was marked as Roxane Exhibit --</p> <p>7 THE WITNESS: 254?</p> <p>8 BY MR. GORTNER:</p> <p>9 Q. 254, thank you. Before we kind of</p> <p>10 delve into that right now, just so I can</p> <p>11 understand, that the -- as you stated in your</p> <p>12 declaration, the reason why you believe that</p> <p>13 Palmetto classified this drug as a brand was</p> <p>14 because of the trade name NovaPlus, right?</p> <p>15 MR. FAUCI: Object to the form.</p> <p>16 THE WITNESS: Right.</p> <p>17 BY MR. GORTNER:</p> <p>18 Q. Okay. Let's take a look now at Roxane</p> <p>19 Exhibit 254 and I just want to go back to what's</p> <p>20 on Page 368 of this Redbook and orient you again</p> <p>21 to that middle column where the six NDC's are</p> <p>22 located underneath Roxane as a manufacturer. Do</p>	<p style="text-align: right;">136</p> <p>1 objection, counsel?</p> <p>2 MR. FAUCI: You would classify -- I</p> <p>3 think it invented assumption and maybe -- if you</p> <p>4 want, I can get into it. Is your question that</p> <p>5 if she was looking at the 2001 printed Redbook,</p> <p>6 would she classify these --</p> <p>7 MR. GORTNER: Yes, yes.</p> <p>8 BY MR. GORTNER:</p> <p>9 Q. Based upon the 2001 annual Redbook that</p> <p>10 was marked as Roxane Exhibit 254, using either of</p> <p>11 the criteria we've testified about how Palmetto</p> <p>12 was classifying drugs, isn't it correct that you</p> <p>13 would classify those three 8404 NDC's, the Roxane</p> <p>14 NovaPlus Ipratropium Bromide, as a generic</p> <p>15 product, not a brand?</p> <p>16 <b>A. If this was all we were looking at, yes.</b></p> <p>17 Q. Yes. And the reason you'd do that is</p> <p>18 because there is no trade name of NovaPlus</p> <p>19 anywhere in this listing, correct?</p> <p>20 <b>A. Correct.</b></p> <p>21 Q. And the reason you do that under the</p>
<p style="text-align: right;">135</p> <p>1 you see that?</p> <p>2 <b>A. Um-hum.</b></p> <p>3 Q. And I'll represent to you that the last</p> <p>4 three NDC's, the ones that have 8404 in the</p> <p>5 middle, those pertain to the NovaPlus label --</p> <p>6 <b>A. Um-hum.</b></p> <p>7 Q. -- Ipratropium Bromide and the top</p> <p>8 three are the Roxane labeled generic product,</p> <p>9 right?</p> <p>10 <b>A. Um-hum.</b></p> <p>11 Q. Okay. Now, the word NovaPlus cannot be</p> <p>12 found on this particular listing, right?</p> <p>13 <b>A. That's right.</b></p> <p>14 Q. So using either criteria that we've</p> <p>15 talked about before, using the criteria that was</p> <p>16 listed in the drug pricing procedure or the</p> <p>17 criteria you've talked about with respect to does</p> <p>18 the name differ from the chemical name, you would</p> <p>19 classify these three NDC's as generics, wouldn't</p> <p>20 you?</p> <p>21 MR. FAUCI: Object to the form.</p> <p>22 MR. GORTNER: What's the basis of your</p>	<p style="text-align: right;">137</p> <p>1 desk procedure is because there is no</p> <p>2 capitalization above Roxane with the generic name</p> <p>3 listed in small caps underneath it, right?</p> <p>4 <b>A. Right.</b></p> <p>5 Q. So it's fair to say then the</p> <p>6 classification of Ipratropium Bromide NovaPlus as</p> <p>7 a generic or a brand depends on what particular</p> <p>8 version of Redbook you're looking at, right?</p> <p>9 <b>A. From the classification, yes.</b></p> <p>10 Q. Yes. If you're looking at the annual</p> <p>11 Redbook, you would classify Ipratropium Bromide</p> <p>12 NovaPlus as a generic, wouldn't you?</p> <p>13 <b>A. If we had not known of the other</b></p> <p>14 <b>situation, yes.</b></p> <p>15 Q. And if you were looking at the Redbook</p> <p>16 CD under your criteria in terms of looking at</p> <p>17 whether it had a trade name, you would classify</p> <p>18 it as a brand, correct?</p> <p>19 <b>A. Correct.</b></p> <p>20 Q. But they're both materials from the</p> <p>21 same Redbook publishing compendia, correct?</p> <p>22 <b>A. I understand that.</b></p>

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Columbia, SC

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36 (Pages 138 to 141)

<p style="text-align: right;">138</p> <p>1 Q. Yes is the answer, correct? 2 <b>A. Yes.</b> 3 Q. Now, with respect to these Redbook 4 CD's, Mrs. Stone, where were the Redbook CD's 5 that you produced this summer? Where were they 6 located? 7 <b>A. They were stored down in some boxes</b> 8 <b>that were packed up from a move or something and</b> 9 <b>there was like a storage area and they were in</b> 10 <b>that.</b> 11 Q. And did you find any printouts of the 12 sort that I showed you in Miss Helton's 13 production to us recently? 14 <b>A. We didn't normally print them out</b> 15 <b>unless somebody asked for information related to</b> 16 <b>a specific drug. It wasn't our practice to print</b> 17 <b>out the CD information when we performed</b> 18 <b>calculations.</b> 19 Q. Did anyone ever ask you to search for 20 the Redbook CD's prior to sometime this summer? 21 <b>A. I mean, they had asked us to search for</b> 22 <b>drug stuff, drug information and try and produce</b></p>	<p style="text-align: right;">140</p> <p>1 of whether it should be classified as a brand or 2 generic? 3 <b>A. Yes.</b> 4 Q. So they were certainly related to that 5 issue, weren't they? 6 <b>A. Yes.</b> 7 Q. And how about printed Redbooks, did you 8 look around for printed Redbooks? 9 <b>A. We did search for our printed Redbooks.</b> 10 <b>We had a file but those had been -- well, they --</b> 11 <b>well, I don't know if they did or didn't. We do</b> 12 <b>have some. We didn't have the annual ones, the</b> 13 <b>older ones. I don't know if there's a date</b> 14 <b>cutoff issue or what.</b> 15 Q. And you claim that you used the Redbook 16 CD's beginning at some point in 1999, is that 17 right? 18 <b>A. I think it's somewhere around 1999. I</b> 19 <b>can't recall the exact date for -- I don't know</b> 20 <b>the exact date. Let's see.</b> 21 Q. I'm looking at the bottom of Page 3, 22 Paragraph 10, if that helps you.</p>
<p style="text-align: right;">139</p> <p>1 <b>everything. But the CD's, I don't know why they</b> 2 <b>weren't, you know, put up for production, I don't</b> 3 <b>know, you know, they were, like I said, when we</b> 4 <b>went back through stuff, we just recently began</b> 5 <b>cleaning out a bunch of our old DMERC records and</b> 6 <b>they were in that stuff. I don't know if someone</b> 7 <b>saw them before and didn't think anything about</b> 8 <b>it or what, I didn't personally go through</b> 9 <b>everything in our files.</b> 10 Q. But if I had asked you to identify for 11 me materials that were related to the pricing 12 these arrays, would the Redbook CD's be materials 13 that you would consider to be related to this 14 project? 15 MR. FAUCI: Object to the form. 16 THE WITNESS: They were used to 17 calculate the fees. The information, however, is 18 reproduced in the fee calculations. 19 BY MR. GORTNER: 20 Q. But in terms of classifying drugs as 21 brands or generics, were the CD's used at least 22 in some point in time to make the determination</p>	<p style="text-align: right;">141</p> <p>1 <b>A. Where are you?</b> 2 MR. FAUCI: He's in your affidavit. 3 THE WITNESS: Oh, okay. I don't have a 4 page number. Okay. 5 BY MR. GORTNER: 6 Q. That's okay, I just wanted to establish 7 that at some point you transitioned. 8 <b>A. Yeah, I'm sure whatever dates I put in</b> 9 <b>there are based on what information I had</b> 10 <b>available to me. I don't remember what I put in</b> 11 <b>there.</b> 12 Q. But it looks like during the time that 13 the Ipratropium Bromide NovaPlus was in the 14 arrays, which was at some point after 1999 I'll 15 represent to you, these Redbook CD's would have 16 been the material that someone looked at to make 17 the determination of whether this drug should be 18 a brand or generic, correct? 19 <b>A. Correct.</b> 20 Q. And these were at Palmetto in storage 21 the whole time, is that what you were saying? 22 <b>A. The CD's, yes.</b></p>

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<p style="text-align: right;">142</p> <p>1 Q. The CD's were. So all the ones that 2 have been produced over the summer, were they in 3 a basement or were they off site?</p> <p>4 <b>A. They were -- we have a reference 5 workstation that just has tons of stuff stored in 6 it and they were in those -- in that stuff boxed 7 up.</b></p> <p>8 Q. How did you find them?</p> <p>9 <b>A. Going through -- we are focusing on 10 procedures to make sure we don't have, what do 11 you call it, PHI -- PII and going through all of 12 that. We had to go through and tear everything 13 apart and they were discovered during that time.</b></p> <p>14 Q. You don't have an index that you keep 15 of stuff in storage?</p> <p>16 <b>A. No.</b></p> <p>17 Q. Now, there was one quarter with respect 18 to Palmetto's classification of Ipratropium 19 Bromide NovaPlus where you weren't sure whether 20 it was classified as a brand or a generic; isn't 21 that right?</p> <p>22 <b>A. I'm not positive about that.</b></p>	<p style="text-align: right;">144</p> <p>1 certainty whether they were treated as brands or 2 generics?</p> <p>3 <b>A. Yes, I stand by that, I just can't 4 remember why.</b></p> <p>5 Q. Later on in the declaration you --</p> <p>6 Paragraph 14, Page 5, Mrs. Stone, you explain a 7 little bit more --</p> <p>8 <b>A. Okay.</b></p> <p>9 Q. -- as to why you're unable to determine 10 whether there were --</p> <p>11 <b>A. Oh, okay.</b></p> <p>12 Q. My question is just a limited question 13 that there is that one quarter where you can't 14 say with certainty whether it was treated as a 15 brand or a generic in the Palmetto arrays?</p> <p>16 <b>A. I would say yes. I know there was a 17 situation I found something else that -- but I 18 can't remember if it's in reference to this and 19 if it was found after this or not.</b></p> <p>20 Q. Do you have any reason to believe that 21 what you stated in that declaration --</p> <p>22 <b>A. There was a file that I came across and</b></p>
<p style="text-align: right;">143</p> <p>1 Q. If you want to, you could look at 2 Paragraph 6 of your affidavit from Pages 2 to 3 really the last sentence at the top of Page 3 4 from Paragraph 6 where you say for one quarter of 5 2003, Q2, I am unable to determine with certainty 6 whether they, meaning the Ipratropium Bromide 7 NovaPlus products, were treated as brands or 8 generics in the fee calculation, right?</p> <p>9 <b>A. That statement is in reference to a 10 file that wasn't classified under our normal 11 working files and that was a period I think -- 12 well, you know what, 2003, I'd have to see what 13 it is I'm referring to again. I don't recall.</b></p> <p>14 Q. I'm just looking at -- I mean, you 15 understand this declaration is --</p> <p>16 <b>A. I'm sure I had reason to state that.</b></p> <p>17 Q. Well, I hope so. This is testimony to 18 the court, you know that, right?</p> <p>19 <b>A. Yeah.</b></p> <p>20 Q. Okay. So you stand by that you were 21 unable to determine for that Quarter 2003, 22 Quarter 2, you were unable to determine with</p>	<p style="text-align: right;">145</p> <p>1 <b>I can't remember if it was after this or not that 2 wasn't -- it was an Excel spreadsheet and it had 3 a brand generic indicator in there. And if I 4 recall, it had a Y for NovaPlus as being a brand 5 but I can't remember if this was the same -- if 6 this was related or not.</b></p> <p>7 Q. Okay. So as we sit here today, are you 8 standing by what you submitted in this 9 declaration on July 23rd, 2009 that for the 10 second quarter of 2003 you cannot say with 11 certainty whether Palmetto classified the 12 NovaPlus product as a generic or a brand?</p> <p>13 <b>A. On that day -- like I said, on that 14 day, I mean, what is in here would be true.</b></p> <p>15 Q. You understand that that's a document 16 that's before the court --</p> <p>17 <b>A. Yeah.</b></p> <p>18 Q. Let me finish my question. And we have 19 a hearing next Tuesday and this is part of the 20 testimonial record of this case.</p> <p>21 <b>A. I know.</b></p> <p>22 Q. So you understand that this is a</p>

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<p style="text-align: right;">146</p> <p>1 significant matter for my client, that we're 2 counting on your representations in this 3 declaration to be true and correct, not just as 4 of July 23rd but as of today. Now, can you say 5 with certainty whether that statement in those 6 Paragraphs 18 and 14 are, in fact, correct as of 7 today?</p> <p>8 MR. FAUCI: What paragraphs are you 9 talking about, Eric?</p> <p>10 MR. GORTNER: I'm referring to, I'm 11 sorry, Paragraphs 6 and 14. Thank you, Jeff.</p> <p>12 MR. FAUCI: I believe I have a copy of 13 this exhibit, of this declaration with the 14 exhibits. I see that Paragraph 14 refers to 15 Exhibit E and that is not here. Would you prefer 16 I substitute that in?</p> <p>17 MR. GORTNER: That's fine, I'm happy to 18 include Exhibit E if that would help clarify the 19 testimony. Would it help you, Miss Stone?</p> <p>20 THE WITNESS: Yes.</p> <p>21 MR. GORTNER: Okay, why don't we take a 22 quick break and we'll bring that in here, we can</p>	<p style="text-align: right;">148</p> <p><b>A. Correct.</b> 1 Q. With respect to Palmetto's drug pricing 2 policies, Palmetto for a period of time also 3 reviewed and submitted payments for Medicare Part 4 B drugs that weren't covered under the DMERC 5 coverage, is that correct?</p> <p><b>A. Payment for drugs that were part of our Part B carrier?</b> 1 Q. Right.</p> <p><b>A. South Carolina carrier?</b> 1 Q. Right. Palmetto also processed -- 2 there was a DMERC --</p> <p><b>A. Right.</b> 1 Q. -- Palmetto.</p> <p><b>A. And as a Part B carrier we processed.</b> 1 Q. And a Part B carrier?</p> <p><b>A. Yes.</b> 1 Q. Can you explain to me in terms of was 2 the Part B carrier located in the same premises 3 as the DMERC carrier or were these different 4 offices?</p> <p><b>A. They were the same.</b></p>
<p style="text-align: right;">147</p> <p>1 clarify that.</p> <p>2 VIDEO TECHNICIAN: We will now go off 3 the record. The time is 2:49 PM.</p> <p>4 (A recess transpired.)</p> <p>5 VIDEO TECHNICIAN: We are now back on 6 the record. The time is 2:59 PM.</p> <p>7 BY MR. GORTNER:</p> <p>8 Q. Mrs. Stone, at the break and right 9 before the break we were discussing Paragraph 6 10 and 14 of your declaration submitted in this case 11 and we provided you with Exhibit E to help 12 clarify the issue. Has it helped you?</p> <p>13 <b>A. Yes. Yes.</b></p> <p>14 Q. And can you clarify whether it's still 15 the case that you cannot determine with certainty 16 whether NovaPlus Ipratropium Bromide was 17 classified as a brand or generic for the second 18 quarter of 2003?</p> <p>19 <b>A. That is true.</b></p> <p>20 Q. What that means is it's possible that 21 it was treated as a brand for that particular 22 quarter or you don't know one way or the other?</p>	<p style="text-align: right;">149</p> <p>1 Q. Same office?</p> <p>2 <b>A. Um-hum.</b></p> <p>3 Q. And did you interact much with the Part 4 B folks that were creating arrays for the Part B 5 drugs?</p> <p>6 <b>A. Yes.</b></p> <p>7 Q. And were they subject to the same 8 policies that we have talked about earlier in 9 terms of determining whether a product should be 10 classified as a generic or a brand?</p> <p>11 <b>A. As far as I can recall, yes.</b></p> <p>12 Q. And you can't think of any reason why 13 Palmetto's Part B employees should be 14 constructing arrays with respect to generics or 15 brands differently than the DMERC employees 16 should be doing it, right?</p> <p>17 <b>A. Not that I can think of. There were variations but I can't recall the different exceptions each time.</b></p> <p>18 Q. How about with respect to NovaPlus? I 19 mean, you've testified here repeatedly that --</p> <p>20 <b>A. Pretty much I think products, the</b></p>

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<p style="text-align: right;">150</p> <p>1 product situation to determine a brand was the 2 same but they are two different groups who were 3 doing those calculations.</p> <p>4 Q. I wanted to show you an exhibit that we 5 can mark as Roxane 259.</p> <p>6 (Exhibit Roxane 259, Document entitled 7 Diltiazem HCL, was marked for identification.)</p> <p>8 BY MR. GORTNER:</p> <p>9 Q. And I'll represent to you that this is 10 a document that was produced in this litigation 11 from the Palmetto carrier and it appears to be an 12 array for a product called Diltiazem. I think it 13 was done by the Palmetto Part B carrier. And as 14 you see, it's a December 2002 date, right?</p> <p>15 A. <b>Um-hum.</b></p> <p>16 Q. And as you can see in the top portion 17 it shows the product manufacturer and appears to 18 have a brand name column and then in the next 19 lower portion it has a generics, do you see that?</p> <p>20 A. <b>Um-hum.</b></p> <p>21 Q. And you can see that in the generics 22 bottom portion of the array, there is an entry</p>	<p style="text-align: right;">152</p> <p>1 generics but, like I said, I don't know the 2 source, I don't know who. There's no --</p> <p>3 Q. You've never seen a document like this 4 before?</p> <p>5 A. <b>Yes, I have seen the document, that's</b> 6 <b>what I'm saying, I don't know -- I don't -- what</b> 7 <b>I've seen is not part of the final file</b> 8 <b>calculations, it's like a working file and it</b> 9 <b>appeared to be an incomplete file because at that</b> 10 <b>time there was another file, the SDP calculation</b> 11 <b>file that would have had this drug in it that --</b></p> <p>12 Q. With respect to this particular 13 document that I handed you that we've marked as 14 Roxane 259, do you contend that this is a 15 nonfinal document with respect to the 16 categorization of the Diltiazem NovaPlus as a 17 generic versus a brand?</p> <p>18 A. <b>I would say that it most likely is</b> 19 <b>because of the NovaPlus being down in the</b> 20 <b>generics. Without -- like I said, without going</b> 21 <b>back and looking at the context of the file and</b> 22 <b>where it fell in our files, I can't say for</b></p>
<p style="text-align: right;">151</p> <p>1 for Diltiazem HCL NovaPlus.</p> <p>2 A. <b>Um-hum.</b></p> <p>3 Q. There's two different NDC's there. Now, 4 would this indicate to you that the Medicare Part 5 B Palmetto carrier had classified that Diltiazem 6 NovaPlus as a generic product and not a brand?</p> <p>7 A. <b>I can't -- I don't know the source name</b> 8 <b>from this so without knowing that, I can't say</b> 9 <b>for certainty because of the date that's December</b> 10 <b>2002 that is when we entered into SDP. I think I</b> 11 <b>had looked at this before and it was not clear</b> 12 <b>that it was a final file or product. This was</b> 13 <b>not part of the SDP files that were being</b> 14 <b>calculated at that time for going into January</b> 15 <b>2003 so I cannot say with certainty why it's</b> 16 <b>showing down here in the generics without</b> 17 <b>actually knowing what files this came from.</b></p> <p>18 Q. But do you have any reason to believe 19 that they did not classify this drug with a 20 NovaPlus name in its title as a generic drug in 21 their arrays?</p> <p>22 A. <b>In the file it is listed there as</b></p>	<p style="text-align: right;">153</p> <p>1 <b>certain.</b></p> <p>2 Q. And that's the basis of your question 3 this document that NovaPlus is categorized in 4 generics rather than brand?</p> <p>5 A. <b>Yes, in this document it is.</b></p> <p>6 Q. How about the Amerinet, the two 7 Amerinet names directly above from Abbott? Do 8 you see that there's a product name that has the 9 Diltiazem, HCL and Amerinet, those are also in 10 the generic field as well, right?</p> <p>11 A. <b>Right.</b></p> <p>12 Q. And you'd expect those to be in the 13 brand according to your criteria?</p> <p>14 A. <b>I would think so, yes.</b></p> <p>15 Q. Now, were you aware that there are 16 instances where the Cigna DMERC -- excuse me, the 17 Cigna Part B carrier also placed NovaPlus 18 products, products that had the name NovaPlus in 19 addition to the generic chemical name, in its 20 generic arrays and not its brand arrays?</p> <p>21 A. <b>I didn't work with Cigna's Part B</b> 22 <b>carrier.</b></p>

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<p>154</p> <p>1 Q. So you didn't know that?</p> <p>2 <b>A. Hum-um.</b></p> <p>3 Q. But if, in fact, Cigna's Part B carrier</p> <p>4 had classified some products with the generic</p> <p>5 chemical name and NovaPlus in the title as a</p> <p>6 generic and not a brand, would that change your</p> <p>7 belief that these should be brands?</p> <p>8 <b>A. We probably would have questioned it</b></p> <p>9 <b>and, you know, taken it again for discussion to</b></p> <p>10 <b>determine, you know, what's right or what's</b></p> <p>11 <b>wrong.</b></p> <p>12 Q. I'll represent to you that it appears</p> <p>13 from the evidence in this case that there have</p> <p>14 been instances where Part B carriers have</p> <p>15 classified a product that has a generic chemical</p> <p>16 name and the term NovaPlus in the title as a</p> <p>17 generic and not a brand drug, okay?</p> <p>18 <b>A. Okay.</b></p> <p>19 Q. And you also know that one of your</p> <p>20 fellow DMERC's classified a drug with the generic</p> <p>21 chemical name NovaPlus as a generic drug for</p> <p>22 years in its arrays, you know that, right?</p>	<p>156</p> <p>1 <b>A. The arrays?</b></p> <p>2 Q. Yeah, the actual Excel sheets here or</p> <p>3 other sheets within Roxane 46 that list, you</p> <p>4 know, particular manufacturer, product name, the</p> <p>5 AWP, whether it's been placed in a generic or</p> <p>6 brand column.</p> <p>7 <b>A. Not that I can recall.</b></p> <p>8 Q. You don't have any reason to believe</p> <p>9 that these were publicly available, do you?</p> <p>10 <b>A. Um-um.</b></p> <p>11 Q. You have to answer yes or no.</p> <p>12 <b>A. No.</b></p> <p>13 Q. The answer is no? So as far as you</p> <p>14 know, Roxane couldn't determine whether Palmetto</p> <p>15 was putting Ipratropium Bromide product in a</p> <p>16 generic or brand array, is that right?</p> <p>17 <b>A. That's correct.</b></p> <p>18 Q. And the same goes for the Ipratropium</p> <p>19 Bromide NovaPlus product, Roxane couldn't</p> <p>20 determine whether you had placed it in the brand</p> <p>21 or generic portion of the array?</p> <p>22 <b>A. That's correct.</b></p>
<p>155</p> <p>1 <b>A. Now I do.</b></p> <p>2 Q. Okay. And you, yourself, aren't sure</p> <p>3 that for that one quarter whether the NovaPlus</p> <p>4 product was classified as a branded drug -- a</p> <p>5 branded generic even within Palmetto, correct?</p> <p>6 <b>A. I can't determine that and say for</b></p> <p>7 <b>certainty because the brand -- there's no brand</b></p> <p>8 <b>or generic indicator on that particular report.</b></p> <p>9 Q. Now, the arrays that we've been</p> <p>10 discussing, and we earlier provided you with a</p> <p>11 Roxane Exhibit 46 which was a collection of</p> <p>12 Palmetto arrays that had been produced in this</p> <p>13 case to us. It's that document right there. It</p> <p>14 has a cover note on it but in the back is a</p> <p>15 collection of the arrays generally from 1996</p> <p>16 through 2004. Maybe you can flip to that</p> <p>17 document quickly and see if you recognize the</p> <p>18 arrays that are behind that.</p> <p>19 Now, Mrs. Stone, let me ask you a</p> <p>20 general question about these arrays. Were these</p> <p>21 particular arrays published on a Web site or in a</p> <p>22 newsletter from 2000 and 2004?</p>	<p>157</p> <p>1 Q. I wanted to draw your attention</p> <p>2 specifically to AWQ022-0038 (sic) and that</p> <p>3 appears to be the 2001 first quarter array. And</p> <p>4 in your declaration you indicated that this was</p> <p>5 the first array where the NovaPlus product was</p> <p>6 entered in the Palmetto arrays. And do you see</p> <p>7 it there under the J code 7644KO?</p> <p>8 MR. FAUCI: Which Bates number?</p> <p>9 BY MR. GORTNER:</p> <p>10 Q. I'm sorry, it's AWQ022-0038.</p> <p>11 <b>A. Oh, 38.</b></p> <p>12 Q. And it appears to be an array for the</p> <p>13 first quarter of 2001 and about three-quarters</p> <p>14 down the page there are three entries for</p> <p>15 Ipratropium Bromide NovaPlus in the array, do you</p> <p>16 see that?</p> <p>17 <b>A. Yes.</b></p> <p>18 Q. And as we talked about on the far right</p> <p>19 next to the three rows of Ipratropium Bromide</p> <p>20 NovaPlus there is a column entitled TYP, which</p> <p>21 might stand for type, and it has a G entry which</p> <p>22 suggests that the fee that was sent was based on</p>

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<p>158</p> <p>1 the median generic AWP, correct?</p> <p>2     <b>A. Correct.</b></p> <p>3     Q. And what I'm asking you to do is just</p> <p>4 to flip through the remaining arrays if you</p> <p>5 wouldn't mind and confirm that in all instances</p> <p>6 where Ipratropium Bromide NovaPlus was in the</p> <p>7 arrays, the payment was set upon the median</p> <p>8 generic AWP and not on a brand AWP.</p> <p>9     And just so that you don't think it's a</p> <p>10 trick question, I represent to you that we have</p> <p>11 gone through it and we see G's next to every</p> <p>12 entry.</p> <p>13     MR. FAUCI: I thought we answered that.</p> <p>14     BY MR. GORTNER:</p> <p>15     Q. Yeah. If you'll stipulate to that, I</p> <p>16 just want to make it clear that that was the case</p> <p>17 and I'll ask a follow-up question so we have it</p> <p>18 clear on the record, Mrs. Stone.</p> <p>19     <b>A. Okay. That appears to be the case.</b></p> <p>20     Q. That's the case? And that indicates to</p> <p>21 you that Ipratropium Bromide NovaPlus AWP never</p> <p>22 set the payment rate for Palmetto's fee</p>	<p>160</p> <p>1 Helton about her declaration in this case?</p> <p>2     <b>A. No.</b></p> <p>3     MR. GORTNER: Okay. And I'm going to</p> <p>4 request that counsel not discuss your testimony</p> <p>5 with Miss Helton prior to her deposition this</p> <p>6 Friday and I'll make the same request of you.</p> <p>7 We'll be speaking with her on Friday and would</p> <p>8 like to keep this testimony private until that</p> <p>9 time. No more questions, thanks.</p> <p>10           EXAMINATION</p> <p>11           BY MR. FAUCI:</p> <p>12     Q. Mrs. Stone, I just have a couple quick</p> <p>13 questions just following up on a few matters.</p> <p>14 I'm going to show you what I'll mark as US Stone</p> <p>15 Exhibit 1.</p> <p>16     (Exhibit US Stone 001, Document</p> <p>17 entitled Tab 171, with attachments, was marked</p> <p>18 for identification.)</p> <p>19     BY MR. FAUCI:</p> <p>20     Q. Take a moment to familiarize yourself</p> <p>21 with that document and just tell me if you</p> <p>22 recognize it.</p>
<p>159</p> <p>1 calculation for Ipratropium Bromide, is that</p> <p>2 correct?</p> <p>3     <b>A. That's correct.</b></p> <p>4     MR. GORTNER: I don't think I have any</p> <p>5 further questions. Thank you for your time.</p> <p>6     MR. FAUCI: Marisa?</p> <p>7     MS. LORENZO: I have no questions.</p> <p>8     MR. GORTNER: Marisa?</p> <p>9     VIDEO TECHNICIAN: We will now go off</p> <p>10 the record. The time is approximately 3:17 PM.</p> <p>11     (A recess transpired.)</p> <p>12     VIDEO TECHNICIAN: We are back on the</p> <p>13 record at 3:24 PM.</p> <p>14     BY MR. GORTNER:</p> <p>15     Q. Mrs. Stone, I have just a couple more</p> <p>16 questions.</p> <p>17     <b>A. Okay.</b></p> <p>18     Q. First, have you spoken to anyone else</p> <p>19 aside from your counsel or the DOJ attorneys with</p> <p>20 respect to your declaration?</p> <p>21     <b>A. No.</b></p> <p>22     Q. Have you had any contact with Miss</p>	<p>161</p> <p>1     <b>A. Yes, I do.</b></p> <p>2     Q. What is this document?</p> <p>3     <b>A. It is a CMS and/or HCFA, at that time,</b></p> <p>4 <b>transmittal which gives the contractors</b></p> <p>5 <b>guidelines and guidance for handling drug</b></p> <p>6 <b>payments.</b></p> <p>7     Q. What's the date of the document?</p> <p>8     <b>A. December 1998.</b></p> <p>9     Q. Do you believe that Palmetto, excuse</p> <p>10 me, received this document?</p> <p>11     <b>A. Yes.</b></p> <p>12     Q. Can you -- can I direct your attention</p> <p>13 to the heading calculation of the AWP? Do you</p> <p>14 see that about midway down?</p> <p>15     <b>A. Oh, yes.</b></p> <p>16     Q. Can you read the language after the</p> <p>17 Number 2?</p> <p>18     <b>A. Okay. For a multisource drug or</b></p> <p>19 <b>biological, the AWP is equal to the lesser of the</b></p> <p>20 <b>median AWP of all of the generic forms of the</b></p> <p>21 <b>drug or biological or the lowest brand name</b></p> <p>22 <b>product AWP. A brand name product is defined as a</b></p>

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<p>1 product that is marketed under a labeled name  2 that is other than the generic chemical name for  3 the drug or biological.</p> <p>4 Q. Are you familiar with this language?</p> <p>5 A. Yes.</p> <p>6 Q. Did you rely on this language in  7 deciding whether to classify products as brand or  8 generics?</p> <p>9 MR. GORTNER: Objection, form.</p> <p>10 THE WITNESS: I'm sure we would have  11 used this in that determination.</p> <p>12 BY MR. FAUCI:</p> <p>13 Q. Earlier you testified that at some  14 point in time you came to understand that there  15 were some products that were what you called  16 branded generics. Do you recall that testimony?</p> <p>17 A. Yes.</p> <p>18 Q. Did you rely on the language in this --  19 the language you just read in determining whether  20 products you regarded as branded generics were  21 brands or generics for purposes of Medicare  22 reimbursement?</p>	<p>1 believe sometime in 2001 or 2002 maybe. I can't  2 remember dates exactly.</p> <p>3 Q. Is that the Redbook for Windows?</p> <p>4 A. No.</p> <p>5 Q. I'm sorry, I misspoke then.</p> <p>6 A. Okay.</p> <p>7 Q. I wasn't clear. Can you tell me the  8 time that you came to use the Redbook for Windows  9 program?</p> <p>10 A. The Redbook for Windows, I want to  11 think -- because I say that in my thing. I can't  12 remember dates very well. I know at least 1999  13 and I think I have something that showed me that  14 we were using it possibly before that but I'm not  15 sure. Hang on. This was dated '99.</p> <p>16 Q. Yeah, if I can -- I believe you're  17 looking at what's been marked as Abbott Exhibit  18 42 -- Roxane Exhibit 42, is that correct?</p> <p>19 A. Yes.</p> <p>20 Q. And I direct your attention to a page  21 on that beginning drug pricing procedure.</p> <p>22 A. Okay.</p>
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<p>1 MR. GORTNER: Objection, form.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. FAUCI:</p> <p>4 Q. I believe you testified earlier as to  5 the sources of information that Palmetto used in  6 determining Medicare reimbursement. Do you  7 recall that?</p> <p>8 A. I'm sorry, repeat that.</p> <p>9 Q. I believe you testified earlier as to  10 the sources and information that Palmetto looked  11 to in determining Medicare reimbursement amounts?</p> <p>12 A. Yes.</p> <p>13 Q. Was that the Redbook?</p> <p>14 A. Yes.</p> <p>15 Q. And you testified that you used  16 different versions of the Redbook, is that  17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. Was there a time -- what was the time  20 that you came to use an on-line version of the  21 Redbook?</p> <p>22 A. The on-line? Oh, gosh. I want to</p>	<p>1 Q. Does this suggest to you that you were  2 using the Redbook CD/ROM by 1999?</p> <p>3 A. Yes.</p> <p>4 Q. In the printed Redbook, were these  5 conventions that Redbook used to distinguish  6 between brand name and generic products?</p> <p>7 A. In the?</p> <p>8 Q. In the annual printed Redbook.</p> <p>9 A. In the annual printed Redbook, yes.</p> <p>10 Q. What were those conventions?</p> <p>11 A. I'd have to look at a visual. The  12 brand name -- can I refer to --</p> <p>13 Q. Do they refer to the type face and  14 capitalization?</p> <p>15 A. Well, yes.</p> <p>16 Q. And were there any such conventions in  17 the Redbook for Windows program?</p> <p>18 A. In the Redbook for Windows? Say the  19 question again, I'm sorry.</p> <p>20 Q. Can you just -- when you looked at  21 pricing information on the Redbook for Windows  22 programs, did it make any -- did it distinguish</p>

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<p style="text-align: right;">166</p> <p>1 between products as brands or generics according 2 to capitalization or type face?</p> <p>3     <b>A. I don't think that was very clear as</b> 4     <b>far as brand and generic. There was</b> 5     <b>capitalization in lower-case -- or upper-case and</b> 6     <b>lower-case and I know one contained all and I</b> 7     <b>can't remember what the other one contained. I</b> 8     <b>looked at it but I can't remember.</b></p> <p>9     Q. Can you look at that exhibit that we 10 marked as Roxane Exhibit 255? I think it was a 11 two-part exhibit. I believe you testified 12 earlier that the information contained in here 13 was -- represents printouts from the Redbook for 14 Windows program?</p> <p>15     <b>A. Yes.</b></p> <p>16     Q. Can I direct your attention to the page 17 marked Cigna 0110.</p> <p>18     <b>A. Okay.</b></p> <p>19     Q. What is this page?</p> <p>20     <b>A. It is a page out of the CD Redbook for</b> 21     <b>Windows.</b></p> <p>22     Q. Does this list various products that</p>	<p style="text-align: right;">168</p> <p>1     MR. FAUCI: No problem. 2     THE WITNESS: Okay. 3     BY MR. FAUCI: 4     Q. This document lists various Diltiazem 5 products and it appears to list several Diltiazem 6 products -- Diltiazem NovaPlus products under the 7 generic section. Do you see that?</p> <p>8     <b>A. Yes.</b></p> <p>9     Q. Above the generic section it says 10 package exclusions. What does that mean?</p> <p>11     <b>A. There are certain exclusions that</b> 12     <b>Palmetto GBA would exclude based on what they</b> 13     <b>call special packaging. Preservative-free might</b> 14     <b>be excluded if the code itself didn't indicate</b> 15     <b>preservative-free. That's all I can think of</b> 16     <b>right now but I know there were some -- there are</b> 17     <b>exclusions.</b></p> <p>18     Q. I think this is my -- so is it fair to 19 say that the products listed under package 20 exclusions were not used to calculate in the 21 arrays?</p> <p>22     <b>A. That would be true.</b></p>
<p style="text-align: right;">167</p> <p>1     were included within the relevant HCFA code for 2 Ipratropium Bromide?</p> <p>3     <b>A. Yes.</b></p> <p>4     Q. And does it list Atrovent?</p> <p>5     <b>A. Yes.</b></p> <p>6     Q. And does it also list Ipratropium 7 Bromide products by brand name manufacturers?</p> <p>8     <b>A. Yes.</b></p> <p>9     Q. And it also lists Ipratropium Bromide 10 NovaPlus?</p> <p>11     <b>A. Yes.</b></p> <p>12     Q. Are those products distinguished in any 13 way in terms of capitalization or type face?</p> <p>14     <b>A. No.</b></p> <p>15     Q. Can you look at Roxane Exhibit 259. It 16 was the Diltiazem. I'm sure Mr. Gortner 17 pronounced it better than I did. Diltiazem. 18 Just a point of clarification --</p> <p>19     <b>MR. GORTNER:</b> Can I interrupt you just 20 for a moment? I'm sorry. Could you move your 21 microphone up a little bit higher? Apparently 22 we're -- sorry about that.</p>	<p style="text-align: right;">169</p> <p>1     Q. I think I just have one more line of 2 very quick questions. Mr. Gortner asked you a 3 series of questions about the possibility of 4 products would have other names appearing after 5 the generic chemical names such as CVS or 6 Walgreens. Do you recall that?</p> <p>7     <b>A. Yes.</b></p> <p>8     Q. Have you ever seen a product that -- 9 where the product name had CVS appearing in the 10 product name?</p> <p>11     <b>A. No.</b></p> <p>12     Q. What about Walgreens?</p> <p>13     <b>A. Not that I can recall.</b></p> <p>14     MR. FAUCI: I have no questions.</p> <p>15     MR. GORTNER: No further questions on 16 my end.</p> <p>17     VIDEO TECHNICIAN: This concludes the 18 videotape deposition of Robin Stone, 30(b)(1) and 19 30(b)(6) representative of Palmetto DMERC. The 20 time is approximately 3:35 PM. We are now off 21 the record.</p> <p>22     (The deposition concluded at 3:35 PM.)</p>

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1 CERTIFICATE OF REPORTER  
2

3 I, Terri L. Brusseau, Registered  
4 Professional Reporter and Notary Public for the  
5 State of South Carolina at Large, do hereby certify  
6 that the foregoing transcript is a true, accurate,  
7 and complete record.

8 I further certify that I am neither  
9 related to nor counsel for any party to the cause  
10 pending or interested in the events thereof.

11 Witness my hand, I have hereunto  
12 affixed my official seal this 16th day of October,  
13 2009 at Charleston, Charleston County, South  
14 Carolina.

15

16

17

18

19 \_\_\_\_\_  
20 Terri L. Brusseau, RPR, CRR  
21 My Commission expires  
22 March 24, 2016.